

**The Florida Senate**  
**COMMITTEE MEETING EXPANDED AGENDA**

**HEALTH POLICY**  
**Senator Young, Chair**  
**Senator Passidomo, Vice Chair**

**MEETING DATE:** Tuesday, February 6, 2018  
**TIME:** 11:00 a.m.—12:30 p.m.  
**PLACE:** Pat Thomas Committee Room, 412 Knott Building

**MEMBERS:** Senator Young, Chair; Senator Passidomo, Vice Chair; Senators Benacquisto, Book, Hukill, Hutson, Montford, and Powell

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
1	<b>CS/SB 394</b> Governmental Oversight and Accountability / Bracy (Identical CS/H 309)	Fire Safety; Requiring the Division of State Fire Marshal to establish specified courses as a part of firefighter and volunteer firefighter training and certification; specifying the division's authority to adopt rules for training related to cancer and mental health risks within the fire service, etc.  GO 01/23/2018 Fav/CS HP 02/06/2018 Favorable RC	Favorable Yeas 6 Nays 0
2	<b>SB 524</b> Brandes (Similar CS/H 431)	Influenza Virus and Streptococcal Infections; Requiring a pharmacist testing for and treating the influenza virus and streptococcal infections to maintain patient records using certain standards and for a specified time; requiring a pharmacist seeking to test for and treat the influenza virus and streptococcal infections to obtain certification through a certification program approved by the Board of Pharmacy in consultation with the Board of Medicine and the Board of Osteopathic Medicine, etc.  HP 02/06/2018 Amendment Adopted - Temporarily Postponed AHS AP	Amendment Adopted - Temporarily Postponed
3	<b>SB 758</b> Gibson (Similar H 561)	Diabetes Educators; Redefining the term "health care practitioner" to include diabetes educators; creating part XVII of ch. 468, F.S., entitled "Diabetes Educators"; providing requirements for registration as a diabetes educator; prohibiting an unregistered person from certain activities relating to diabetes self-management training; authorizing the department to take disciplinary action against an applicant or registrant for specified violations, etc.  HP 02/06/2018 Fav/CS AHS AP	Fav/CS Yeas 6 Nays 0

**COMMITTEE MEETING EXPANDED AGENDA**

Health Policy

Tuesday, February 6, 2018, 11:00 a.m.—12:30 p.m.

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TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
4	<b>SB 848</b> Grimsley (Similar CS/H 679)	Remote Dispensing Site Pharmacies; Redefining the term "pharmacy" to include remote dispensing site pharmacies; providing that an offsite pharmacist who supervises a registered pharmacy technician at a remote dispensing site is not considered to be not present or off duty; providing permit requirements for remote dispensing site pharmacies, etc.  HP 02/06/2018 Fav/CS AP RC	Fav/CS Yeas 6 Nays 0
5	<b>SB 1494</b> Montford (Similar CS/H 351)	Prescription Drug Pricing Transparency; Requiring a pharmacist to inform a customer of a lower cost alternative to a prescription and of whether the customer's cost-sharing obligation exceeds the retail price of the prescription; requiring a pharmacy benefit manager to register with the Office of Insurance Regulation, etc.  HP 02/06/2018 Fav/CS BI AP	Fav/CS Yeas 6 Nays 0
6	<b>SB 1508</b> Young (Similar H 1185)	Use of Stem Cells in a Clinic Setting; Requiring a physician or osteopathic physician or a clinic owner to register a clinic with the Department of Health if the clinic meets certain criteria; requiring a physician or osteopathic physician to adhere to specified regulations in the performance of any procedure using or purporting to use stem cells or products containing stem cells, etc.  HP 02/06/2018 Favorable AP RC	Favorable Yeas 6 Nays 0

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Other Related Meeting Documents

**The Florida Senate**  
**BILL ANALYSIS AND FISCAL IMPACT STATEMENT**

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

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Prepared By: The Professional Staff of the Committee on Health Policy

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BILL: CS/SB 394

INTRODUCER: Governmental Oversight and Accountability Committee and Senator Bracy

SUBJECT: Fire Safety

DATE: February 5, 2018      REVISED: \_\_\_\_\_

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Peacock	Caldwell	GO	<b>Fav/CS</b>
2.	Looke	Stovall	HP	<b>Favorable</b>
3.			RC	

**Please see Section IX. for Additional Information:**

COMMITTEE SUBSTITUTE - Substantial Changes

**I. Summary:**

CS/SB 394 amends requirements related to firefighter and volunteer firefighter training and certification to require the Division of the State Fire Marshall (division) within the Department of Financial Services (DFS) to establish in rule training courses for career and volunteer firefighters related to cancer and mental health risks within the fire service. The bill requires that the training be a requirement in order to obtain certain certificates related to firefighting and specifies what must be included in the training.

The bill provides an effective date of July 1, 2018.

**II. Present Situation:**

**Division of the State Fire Marshal**

Chapter 633, F.S., provides state law on fire prevention and control. Section 633.104(1), F.S., designates the Chief Financial Officer (CFO) as the State Fire Marshal, operating through the division.<sup>1</sup> Pursuant to this authority, the State Fire Marshal:

- Regulates, educates or trains, and certifies fire service personnel;<sup>2</sup>

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<sup>1</sup> The head of the DFS is the Chief Financial Officer. The Division of the State Fire Marshal is located within the DFS. See s. 20.121, F.S.

<sup>2</sup> Section 633.128(1), F.S. Also see ch. 633, part IV: Fire Standards and Training, F.S.

- Investigates the causes of fires;<sup>3</sup>
- Enforces arson laws;<sup>4</sup>
- Regulates the installation and maintenance of fire equipment;<sup>5</sup>
- Conducts firesafety inspections of state buildings;<sup>6</sup>
- Develops firesafety standards;<sup>7</sup>
- Provides facilities for the analysis of fire debris;<sup>8</sup> and
- Operates the Florida State Fire College.<sup>9</sup>

Additionally, the State Fire Marshal adopts by rule the Florida Fire Prevention Code, which contains or references all firesafety laws and rules regarding public and private buildings.<sup>10</sup>

The division consists of the two bureaus: the Bureau of Fire Standards and Training (BFST), and the Bureau of Fire Prevention.<sup>11</sup> The Florida Fire College, part of the BFST, trains over 6,000 students per year.<sup>12</sup> The Inspections Section, under the Bureau of Fire Prevention, annually inspects more than 14,000 state-owned buildings and facilities. Over 1.8 million fire and emergency reports are collected every year. These reports are entered into a database to form the basis for the State Fire Marshal's annual report.<sup>13</sup>

### **Firefighters Employment, Standards, and Training Council**

The Firefighters Employment, Standards, and Training Council (council) is housed within the DFS and consists of 14 members.<sup>14</sup> The council is authorized to make recommendations for adoption by the division on:

- Uniform minimum standards for the employment and training of firefighters and training of volunteer firefighters.
- Minimum curriculum requirements for schools operated by or for any fire service provider<sup>15</sup> for the specific purpose of training firefighter trainees, firefighters, and volunteer firefighters.
- Matters relating to the funding, general operation, and administration of the Bureau of Fire Standards and Training (Florida State Fire College), including, but not limited to, all

<sup>3</sup> Sections 633.104(2)(e), and 633.112, F.S.

<sup>4</sup> Section 633.104(2)(e), F.S.

<sup>5</sup> Section 633.104(2)(b), F.S. *Also see* s. 633.104(2)(c), F.S., and ch. 633, part III: Fire Protection and Suppression, F.S.

<sup>6</sup> Section 633.218, F.S.

<sup>7</sup> Chapter 633, part II: Fire Safety and Prevention, F.S.

<sup>8</sup> Section 633.432, F.S.

<sup>9</sup> Section 633.128(1)(h)–(q), F.S. *Also see* ss. 633.428–633.434, F.S.

<sup>10</sup> Section 633.202(1), F.S.

<sup>11</sup> See <https://www.myfloridacfo.com/Division/sfm/> (last visited on Jan. 31, 2018).

<sup>12</sup> See Division of State Fire Marshal, *About the Florida State Fire Marshal*, <http://www.myfloridacfo.com/division/sfm/AbouttheStateFireMarshal.htm> (last visited on Jan. 31, 2018).

<sup>13</sup> *Id.*

<sup>14</sup> Section 633.402(1), F.S.

<sup>15</sup> Section 633.102(13), F.S., defines “fire service provider” as a municipality or county, the state, the division, or any political subdivision of the state, including authorities and special districts, that employs firefighters or uses volunteer firefighters to provide fire extinguishment or fire prevention services for the protection of life and property. The term includes any organization under contract or other agreement with such entity to provide such services.

standards, training, curriculum, and the issuance of any certificate of competency required by ch. 633, F.S.<sup>16</sup>

The council may also make or support studies on any aspect of firefighting employment, education, and training or recruitment.<sup>17</sup>

### **Curriculum Requirements for Firefighters**

A person applying for certification as a firefighter must:

- Be a high school graduate or the equivalent and at least 18 years of age;
- Not have been convicted of a misdemeanor relating to the certification or to perjury or false statements, a felony, a crime punishable by imprisonment of one year or more or be dishonorably discharged from the Armed Forces of the United States;
- Submit a set of fingerprints to the division with a current processing fee;
- Have a good moral character;
- Be in good physical condition as determined by a medical examination; and
- Be a nonuser of tobacco or tobacco products for at least one year immediately preceding application.<sup>18</sup>

The division is responsible for establishing a Minimum Standards Course as the training and educational curriculum required in order for a firefighter to obtain a Firefighter Certificate of Compliance (FCOC).<sup>19</sup> A FCOC is issued by the division to an individual who does all of the following:

- Satisfactorily completes the Minimum Standards Course or has satisfactorily completed training for firefighters in another state which has been determined by the division to be at least the equivalent of the training required for the Minimum Standards Course;
- Passes the Minimum Standards Course examination within 12 months after completing the required courses; and
- Meets the character and fitness requirements in s. 633.412, F.S.<sup>20</sup>

In order for a firefighter to retain or renew his or her FCOC, every four years he or she must:

- Be active as a firefighter;
- Maintain a current and valid fire service instructor certificate, instruct at least 40 hours during the four-year period, and provide proof of such instruction to the division, which proof must be registered in an electronic database designated by the division;
- Within six months before the four-year period expires, successfully complete a Firefighter Retention Refresher Course consisting of a minimum of 40 hours of training to be prescribed by rule; and
- Within six months before the four-year period expires, successfully retake and pass the Minimum Standards Course examination.<sup>21</sup>

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<sup>16</sup> Section 633.402(9), F.S.

<sup>17</sup> *Id.*

<sup>18</sup> Section 633.412, F.S.

<sup>19</sup> Section 633.408(1)(a), F.S.

<sup>20</sup> Section 633.408(4), F.S.

<sup>21</sup> Section 633.414(1), F.S.

## Curriculum Requirements for Volunteer Firefighters

To obtain a Volunteer Firefighter Certificate of Completion, a volunteer firefighter must take of Part I of the Minimum Standards Course as required by ch. 633, F.S., and chs. 69A-37 (Firefighters Standards and Training) and 69A-62 (Firefighter Employment Standards), F.A.C.<sup>22</sup> A significant portion of this training can be completed through on-line and practical skill courses. The on-line courses can be taken in lieu of the traditional classroom lecture and satisfies most of the required academic objectives. The Part I Minimum Standards Course is 206 hours of training as well as the following academic components:<sup>23</sup>

- Firefighter I Curriculum consists of classroom and live fire based core training.
- National Incident Management System focuses on the history, features, principles, and organizational structure of Incident Command.
- Wildland Firefighter Training curriculum and field exercises that address the basic skills required of all wildland firefighters who must understand the behavior and factors that affect the spread of wildfires.
- EMS First Responder curriculum that is an introduction to basic life support and emergency care.

A volunteer firefighter who has successfully completed the Firefighter Part I training may operate in the exclusionary or hot zone<sup>24</sup> and in an Immediately Dangerous to Life or Health environment.<sup>25</sup> In order for volunteer firefighters to retain their Volunteer Firefighter Certificate of Completion, every four years they must serve as a volunteer firefighter or complete a 40-hour refresher course.<sup>26</sup>

## Special Certificate of Compliance

A Special Certificate of Compliance issued by the division authorizes an individual to serve as an administrative and command head of a fire service provider.<sup>27</sup> In order to obtain a Special Certificate of Compliance, an individual must do all of the following:

- Satisfactorily complete Part I of the Minimum Standards Course;
- Pass the Minimum Standards Course examination; and
- Meet the character and fitness requirements in s. 633.412, F.S.<sup>28</sup>

## Cancer and Mental Health in Firefighting

In addition to the dangers of fighting fires, firefighters incur long term risks to their physical and mental well-being in the form of an increased cancer risk and increased mental health issues due

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<sup>22</sup> Guidelines for the Firefighter Part I Certificate of Completion Program (Volunteer Firefighter), Division of State Fire Marshal, *The Bureau of Fire Standards and Training at the Florida State Fire College* (Revision 2.1, March 2017) available at [https://myfloridacfo.com/division/sfm/bfst/Training/REV\\_2\\_1\\_Guidelines\\_FF1.pdf](https://myfloridacfo.com/division/sfm/bfst/Training/REV_2_1_Guidelines_FF1.pdf) (last visited Jan. 21, 2018).

<sup>23</sup> *Id.*

<sup>24</sup> Section 633.102(17), F.S., defines the term “hot zone” as the area immediately around an incident where serious threat of harm exists, which includes the collapse zone for a structure fire.

<sup>25</sup> *See supra* note 23.

<sup>26</sup> Section 633.414(2), F.S.

<sup>27</sup> Section 633.408(6), F.S.

<sup>28</sup> *Id.*

to stress. The National Fire Protection Association warns of a growing body of research and data showing the contributions that job-related exposures have in chronic illnesses, such as cancer and heart disease for firefighters. The National Institute for Occupational Safety and Health recently undertook two large studies focused on firefighter cancer and concluded that firefighters face a 9 percent increase in cancer diagnoses, and a 14 percent increase in cancer-related deaths, compared to the general population in the U.S.<sup>29</sup>

Additionally, the International Association of Firefighters states that:

Traditionally, medical and physical fitness have been prioritized above emotional or behavioral fitness in the Fire Service. However, it is clear from the aftermath of 9/11, Hurricane Katrina, and other disasters that these priorities are now changing. With each passing year, research shows that fire personnel who balance physical, behavioral and emotional fitness have the best outcomes, whether one is looking at adjustment to becoming a fire fighter, ratings of career satisfaction, family well-being, or adjustment to retirement.

There is growing concern about behavioral health issues and the significant impact on wellness. The stresses faced by fire fighters, paramedics and EMTs throughout the course of their careers – incidents involving children, violence, inherent dangers of firefighting, and other potentially traumatic events – can have a cumulative impact on their mental health and well-being.<sup>30</sup>

### III. Effect of Proposed Changes:

**Section 1** amends s. 633.408, F.S., to require the division to establish in rule training courses for career and volunteer firefighters related to cancer and mental health risks within the fire service. The training must be a requirement for obtaining a Firefighter Certificate of Compliance, a Volunteer Firefighter Certificate of Compliance, or a Special Certificate of Compliance and must be made available to certified firefighters. The bill specifies that the training must:

- Include cancer and mental health awareness, prevention, mitigation, and treatment;
- Include lifestyle, environmental, inherited, and occupational risks; and
- Emphasize appropriate behavior, attitude, and cultural changes within the fire service.

**Section 2** amends s. 633.508, F.S., to conform rulemaking authority for the division to include the new training requirement.

**Section 3** establishes an effective date of July 1, 2018.

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<sup>29</sup> National Fire Protection Association, *Firefighters and Cancer* <https://www.nfpa.org/News-and-Research/Resources/Emergency-Responders/Health-and-Wellness/Firefighters-and-cancer> (last visited Feb. 2, 2018).

<sup>30</sup> IAFF Firefighters, *IAFF Behavioral Health Program* <http://client.prod.iaff.org/#page=behavioralhealth> (last visited Feb. 2, 2018).

**IV. Constitutional Issues:**

## A. Municipality/County Mandates Restrictions:

None.

## B. Public Records/Open Meetings Issues:

None.

## C. Trust Funds Restrictions:

None.

**V. Fiscal Impact Statement:**

## A. Tax/Fee Issues:

None.

## B. Private Sector Impact:

None.

## C. Government Sector Impact:

CS/SB 394 may have an indeterminate negative fiscal impact on the division because it will require the division to adjust its training courses and exams to accommodate the training required by the bill.

**VI. Technical Deficiencies:**

None.

**VII. Related Issues:**

None.

**VIII. Statutes Affected:**

This bill substantially amends the following sections of the Florida Statutes: 633.408 and 633.508.

## A. Committee Substitute – Statement of Substantial Changes:

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

**CS by Governmental Oversight and Accountability on January 23, 2018:**

The committee substitute deletes provisions of the original bill that would have revised qualifications for firefighter certification to require firefighter to be a nonuser of tobacco or tobacco products during his or her career in the fire service.



B. Amendments:

None.

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This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.

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923612

LEGISLATIVE ACTION

Senate	.	House
Comm: UNFAV	.	
02/06/2018	.	
	.	
	.	
	.	

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The Committee on Health Policy (Passidomo) recommended the following:

**Senate Amendment (with title amendment)**

Delete lines 19 - 40  
and insert:  
firefighters related to occupational hazards and mental health risks in the fire service. Such training must be a requirement for obtaining a Firefighter Certificate of Compliance, Volunteer Firefighter Certificate of Completion, or Special Certificate of Compliance. The training must include mental health awareness, prevention, mitigation, and treatment. The training must



923612

11 specifically include lifestyle, environmental, inherited, and  
12 occupational risks, and emphasize appropriate behaviors,  
13 attitudes, and cultural changes in the fire service. Certified  
14 firefighters shall have such training made available to them.

15 Section 2. Subsection (2) of section 633.508, Florida  
16 Statutes, is amended to read:

17 633.508 Workplace safety; rulemaking authority; division  
18 authority.—

19 (2) The division shall have the authority to adopt rules  
20 for the purpose of ensuring safe working conditions for all  
21 firefighter employees by authorizing the enforcement of  
22 effective standards, by assisting and encouraging firefighter  
23 employers to maintain safe working conditions, and by providing  
24 for education and training in the field of safety, including  
25 training related to occupational hazards and mental health risks  
26 in the

27  
28 ===== T I T L E A M E N D M E N T =====

29 And the title is amended as follows:

30 Delete line 8

31 and insert:

32 occupational hazards and mental health risks in the  
33 fire

**By** the Committee on Governmental Oversight and Accountability;  
and Senator Bracy

585-02374-18

2018394c1

1                   A bill to be entitled  
2           An act relating to fire safety; amending s. 633.408,  
3           F.S.; requiring the Division of State Fire Marshal to  
4           establish specified courses as a part of firefighter  
5           and volunteer firefighter training and certification;  
6           amending s. 633.508, F.S.; specifying the division's  
7           authority to adopt rules for training related to  
8           cancer and mental health risks within the fire  
9           service; providing an effective date.

10  
11 Be It Enacted by the Legislature of the State of Florida:

12  
13           Section 1. Paragraph (d) is added to subsection (1) of  
14           section 633.408, Florida Statutes, to read:

15           633.408 Firefighter and volunteer firefighter training and  
16           certification.—

17           (1) The division shall establish by rule:

18           (d) Courses to provide training for career and volunteer  
19           firefighters related to cancer and mental health risks within  
20           the fire service. Such training must be a requirement for  
21           obtaining a Firefighter Certificate of Compliance, Volunteer  
22           Firefighter Certificate of Completion, or Special Certificate of  
23           Compliance. The training must include cancer and mental health  
24           awareness, prevention, mitigation, and treatment. The training  
25           must specifically include lifestyle, environmental, inherited,  
26           and occupational risks, and emphasize appropriate behavior,  
27           attitude, and cultural changes within the fire service.  
28           Certified firefighters shall have such training made available  
29           to them.

585-02374-18

2018394c1

30 Section 2. Subsection (2) of section 633.508, Florida  
31 Statutes, is amended to read:

32 633.508 Workplace safety; rulemaking authority; division  
33 authority.—

34 (2) The division shall have the authority to adopt rules  
35 for the purpose of ensuring safe working conditions for all  
36 firefighter employees by authorizing the enforcement of  
37 effective standards, by assisting and encouraging firefighter  
38 employers to maintain safe working conditions, and by providing  
39 for education and training in the field of safety, including  
40 training related to cancer and mental health risks within the  
41 fire service. Specifically, the division may by rule adopt the  
42 most current edition of all or any part of subparts C through T  
43 and subpart Z of 29 C.F.R. s. 1910; the National Fire Protection  
44 Association, Inc., Publication 1403, Standard on Live Fire  
45 Training Evolutions, as limited by subsection (6); and ANSI A  
46 10.4.

47 Section 3. This act shall take effect July 1, 2018.



The Florida Senate

## Committee Agenda Request

**To:** Senator Dana Young, Chair  
Health Policy

**Subject:** Committee Agenda Request

**Date:** January 24, 2018

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I respectfully request that **Senate Bill #394**, relating to Fire Safety, be placed on the:

- committee agenda at your earliest possible convenience.
- next committee agenda.

A handwritten signature in black ink, reading "Randolph Bracy".

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Senator Randolph Bracy  
Florida Senate, District 11

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/6/18  
Meeting Date

SB 344

Bill Number (if applicable)

0123612

Amendment Barcode (if applicable)

Topic FIRE SAFETY

Name JOE PICCOLI

Job Title ~~6992 NW 30th Ave~~ FIRE FIGHTER

Address 6992 NW 30th Ave

Phone 754-234-0806

Street

CITY LAUDERDALE FL 33309

City

State

Zip

Email PALAMEDICALSOC@CMAA.COM

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing \_\_\_\_\_

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

**THE FLORIDA SENATE**  
**APPEARANCE RECORD**

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/6/18  
Meeting Date

SB 394  
Bill Number (if applicable)  
923612  
Amendment Barcode (if applicable)

Topic Fire Safety

Name Paul Cernuda

Job Title Firefighter

Address 2980 NW South River Drive  
Street

Phone 786-306-4719

Miami FL 33125  
City State Zip

Email pcernuda@iaff587.org

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing \_\_\_\_\_

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

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**THE FLORIDA SENATE**  
**APPEARANCE RECORD**

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/6/18  
Meeting Date

394

Bill Number (if applicable)

923612

Amendment Barcode (if applicable)

Topic Fire Safety

Name Rocco Salvatori

Job Title Firefighter

Address 343 W Madison St

Phone 850-224-7333

Street

Tallahassee

FL

32301

Email roccofish@verizon.net

City

State

Zip

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing Florida Professional Firefighters

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

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S-001 (10/14/14)

THE FLORIDA SENATE  
**APPEARANCE RECORD**

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

Feb. 6, 2018

Meeting Date

394

Bill Number (if applicable)

923612

Amendment Barcode (if applicable)

Passive no smdnt.

Topic Fire Safety

Name Otto Dord

Job Title Fire Chief Orange County Fire Rescue

Address 6590 AMERY COURT

Street

Orlando

City

FL

State

Zip

Phone (407) 637-7559

Email otto.dord@ocfr.net

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing Florida Fire Chiefs Association

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

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S-001 (10/14/14)

**THE FLORIDA SENATE**  
**APPEARANCE RECORD**

2-6-18

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

394

Meeting Date

Bill Number (if applicable)

923612

Amendment Barcode (if applicable)

Topic SB 394

Name Eloy Ricardo

Job Title District Vice President

Address 165 Wiloughby Dr

Street

Phone \_\_\_\_\_

Naples

FL

34110

Email \_\_\_\_\_

City

State

Zip

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing Florida Professional Firefighters

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

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S-001 (10/14/14)

**THE FLORIDA SENATE**  
**APPEARANCE RECORD**

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

Feb 4, 18  
Meeting Date

394  
Bill Number (if applicable)

923612  
Amendment Barcode (if applicable)

Topic \_\_\_\_\_

Name ERIC CUBZUK

Job Title PRESIDENT

Address 407 SW 2ND TER  
Street

Phone (239) 560-0930

CAPE CORAL FL 33914  
City State Zip

Email Pol2424@capfl.com

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing CAPE CORAL FIRE FIGHTERS

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

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S-001 (10/14/14)

**THE FLORIDA SENATE**  
**APPEARANCE RECORD**

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/6/18

Meeting Date

SB 394

Bill Number (if applicable)

923612

Amendment Barcode (if applicable)

Topic FIRE SAFETY

Name LAWRITA SWEENEY

Job Title RETIRED FF

Address 1100 KASPER DR.

Street

ORLANDO FL 32801

City

State

Zip

Phone 407-702-4051

Email lawriswe@ocffa.com

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing ORANGE COUNTY FIRE FIGHTER'S ASSOC.

Appearing at request of Chair:  Yes  No Lobbyist registered with Legislature:  Yes  No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

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THE FLORIDA SENATE  
**APPEARANCE RECORD**

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/6/18

Meeting Date

SB 394

Bill Number (if applicable)

923612

Amendment Barcode (if applicable)

Topic Fire Safety

Name DAVID STEPHAN

Job Title Political Committee Chair

Address 6969 Venture Cir  
Street

Phone 407 389 2057

OKLAHOMA  
City

FL  
State

32807  
Zip

Email dabesh1@yale.edu.com

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing Orange County Firefighters Association

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

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S-001 (10/14/14)

**THE FLORIDA SENATE**  
**APPEARANCE RECORD**

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2-6-18

Meeting Date

394

Bill Number (if applicable)

923612

Amendment Barcode (if applicable)

Topic \_\_\_\_\_

Name Michael Lynch

Job Title firefighter

Address 625 Stockton St  
Street

Phone 904-384-1011

JAY  
City

FL  
State

32204  
Zip

Email mlynch@cos.net

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing Jacksonville firefighters

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

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S-001 (10/14/14)

**THE FLORIDA SENATE**  
**APPEARANCE RECORD**

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2-6-18  
Meeting Date

394  
Bill Number (if applicable)  
923612  
Amendment Barcode (if applicable)

Topic \_\_\_\_\_

Name Randy Wyse

Job Title ~~Fire~~ Firefighter

Address 625 Stockton St.  
Street

Phone 904-334-8470

City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_

Email rwyse@csmeast.net

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing Tacksonville Firefighters

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

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**THE FLORIDA SENATE**  
**APPEARANCE RECORD**

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2-5-18

Meeting Date

394

Bill Number (if applicable)

923612

Amendment Barcode (if applicable)

Topic \_\_\_\_\_

Name Chuck Baldwin

Job Title Fire Fighter

Address 625 Stockton St.  
Street

Phone \_\_\_\_\_

City

State

Zip

Email \_\_\_\_\_

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing Jacksonville, FL

Appearing at request of Chair:  Yes  No      Lobbyist registered with Legislature:  Yes  No

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S-001 (10/14/14)

**THE FLORIDA SENATE**  
**APPEARANCE RECORD**

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/6/18  
Meeting Date

SB 394  
Bill Number (if applicable)  
923612  
Amendment Barcode (if applicable)

Topic Fire Safety Amendment

Name Chris Ritchie

Job Title Treasurer

Address 6969 Venture Cir  
Street

Phone 407 389 2057

Orlando FL 32807  
City State Zip

Email Treasurer@ocffa.com

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing Orange County Fire Fighters Association

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

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S-001 (10/14/14)

**THE FLORIDA SENATE**  
**APPEARANCE RECORD**

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/6/18

Meeting Date

SB 394

Bill Number (if applicable)

923612

Amendment Barcode (if applicable)

Topic FINE SAFETY.

Name RICHARD PIERCE

Job Title FIRE FIGHTER

Address 1040 S FL

Street

ROCKLEDGE FL

City

32955

State

Zip

Phone 321 323 6162

Email RICHARD.PIERCE@IAAF2169.COM

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing BREVARD COUNTY FIRE FIGHTER

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

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S-001 (10/14/14)

**THE FLORIDA SENATE**  
**APPEARANCE RECORD**

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/6/18

Meeting Date

SB 394

Bill Number (if applicable)

923612

Amendment Barcode (if applicable)

Topic FIRE SAFETY

Name KURT VROMAN

Job Title \_\_\_\_\_

Address 166 WILDWOOD DR

Street

DEBARY

City

FL

State

32713

Zip

Phone 386-235-6765

Email \_\_\_\_\_

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing DELTONA FIREFIGHTERS

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

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S-001 (10/14/14)

**THE FLORIDA SENATE**  
**APPEARANCE RECORD**

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2-6-18  
Meeting Date

SB 394  
Bill Number (if applicable)  
923612  
Amendment Barcode (if applicable)

Topic Fire Safety

Name Eric Siena

Job Title Vice President

Address 6969 Venture Cr  
Street

Phone 4077389162

Orl FL 32807  
City State Zip

Email VicePresident@coeffac.

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing Orange County Fire Fighters Assoc

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

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**THE FLORIDA SENATE**  
**APPEARANCE RECORD**

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2/6/18

Meeting Date

SB 394

Bill Number (if applicable)

923612

Amendment Barcode (if applicable)

Topic FIRE SAFETY

Name ANDRE PEREZ

Job Title PRESIDENT

Address 6969 VENTURE CIR

Street

ORLANDO, FL

City

State

32807

Zip

Phone 321 276 4719

Email Andreperes2@ocffa.com

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing ORANGE COUNTY FIRE FIGHTERS ASSOC

Appearing at request of Chair:  Yes  No Lobbyist registered with Legislature:  Yes  No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

Meeting Date

SB 394  
Bill Number (if applicable)

923612  
Amendment Barcode (if applicable)

Topic Fire Safety

Name James Pucci

Job Title LEGISLATIVE AFFAIRS LIASON

Address 1310 SW BAYWOOD DR

Phone (772) 336-4366

Street

City Fort St Lucie FL 34986

State

Zip

Email

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing St Lucie Co Firefighters

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

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**THE FLORIDA SENATE**  
**APPEARANCE RECORD**

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/6/18  
Meeting Date

SB 394  
Bill Number (if applicable)

923612  
Amendment Barcode (if applicable)

Topic fire safety

Name Kevin Bellucy

Job Title \_\_\_\_\_

Address 5148 SE miles grant ter

Street

Phone 772-631-2386

stuart

City

FL

State

34997

Zip

Email \_\_\_\_\_

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing St Lucie county firefighters

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

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S-001 (10/14/14)



THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/6/14

Meeting Date

SB 394

Bill Number (if applicable)

9236612

Amendment Barcode (if applicable)

Topic FIRE SAFETY

Name JOE PICCAU

Job Title FIRE FIGHTER

Address 6992 NW 30th AVE

Street

Phone 754-234-0866

FORT LAUDERDALE FL 33309

City

State

Zip

Email PALANED1@JOE@GMAIL.COM

Speaking: [ ] For [ ] Against [ ] Information

Waive Speaking: [X] In Support [ ] Against (The Chair will read this information into the record.)

Representing

Appearing at request of Chair: [ ] Yes [ ] No

Lobbyist registered with Legislature: [ ] Yes [ ] No

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# APPEARANCE RECORD

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2/6/18

Meeting Date

SB 394

Bill Number (if applicable)

923612

Amendment Barcode (if applicable)

Topic

Fire Safety

Name

Eric Johnson

Job Title

Fire Fighter

Address

782 East 102 Ave

Street

Phone

305/970-8820

City

Orlando

State

FL

Zip

32810

Email

where@com

Speaking:

For

Against

Information

Waive Speaking:

In Support

Against

(The Chair will read this information into the record.)

Representing \_\_\_\_\_

Appearing at request of Chair:

Yes

No

Lobbyist registered with Legislature:

Yes

No

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APPEARANCE RECORD

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2/6/18  
Meeting Date

SB 394  
Bill Number (if applicable)

923612  
Amendment Barcode (if applicable)

Topic Fire Safety

Name John O'Brien

Job Title Firefighter

Address 2998 Virginia St

Phone 31389 7621

Street Miami

State FL Zip 33133

Email jo.obrien@fla.gov

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing \_\_\_\_\_

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

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THE FLORIDA SENATE

APPEARANCE RECORD

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2/6/18  
Meeting Date

SB 394  
Bill Number (if applicable)  
923612  
Amendment Barcode (if applicable)

Topic FIRE SAFETY

Name DAN GIVENS

Job Title FIRE TRUSTEE

Address 9941 SW 130 ST

Phone 305 253 2442

Street MIAMI FL 33176  
City State Zip

Email DDGIVENS@BELLSONTHA.NET

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing \_\_\_\_\_

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

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THE FLORIDA SENATE  
**APPEARANCE RECORD**

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2/6/18

Meeting Date

SB 394

Bill Number (if applicable)

923612

Amendment Barcode (if applicable)

Topic Fire Safety

Name Ryan Ventimiglia

Job Title Firefighter

Address 2980 NW 5. River Dr

Street

Phone 786 351 5872

Miami

City

FL

State

33125

Zip

Email CrazeeRyan@aol.com

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing \_\_\_\_\_

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/6/18

Meeting Date

SB 394

Bill Number (if applicable)

923612

Amendment Barcode (if applicable)

Topic Fire Safety

Name DAVIDO PEREZ

Job Title Firefighter

Address 322 E 43 St

Street

Hialeah

City

FL

State

33013

Zip

Phone

Email

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against

(The Chair will read this information into the record.)

Representing Florida Professional Firefighters Local 1210

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

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THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/6/18

Meeting Date

394

Bill Number (if applicable)

923612

Amendment Barcode (if applicable)

Topic FIRE SAFETY

Name OMAR BLANCO

Job Title PRESIDENT - MIAMI DADE FIREFIGHTERS LOCAL 1403

Address 8000 NW 21 ST

Phone 305-593-6100

Street

MIAMI

FL

33122

City

State

Zip

Email

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

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THE FLORIDA SENATE

APPEARANCE RECORD

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2/6/18

Meeting Date

394

Bill Number (if applicable)

923612

Amendment Barcode (if applicable)

Topic FIRE SAFETY

Name JORGE CHAVEZ

Job Title FIRE FIGHTER

Address 8000 NW 21 ST

Phone 305 593-6100

Street

MIAMI

FL

33122

City

State

Zip

Email

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

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# APPEARANCE RECORD

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2/6/2018

Meeting Date

SB 394

Bill Number (if applicable)

923612

Amendment Barcode (if applicable)

Topic FIRE SAFETY

Name ALBERT ROBERT

Job Title FIREFIGHTER

Address 2980 NW SOUTH RIVER DRIVE

Street

Phone 305-965-3636

MIAMI FL 33125

City

State

Zip

Email ALBERT.ROBERT@LIVE.COM

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing \_\_\_\_\_

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

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THE FLORIDA SENATE  
**APPEARANCE RECORD**

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2/6/18  
Meeting Date

SB 394  
Bill Number (if applicable)

Topic Fire Safety

Amendment Barcode (if applicable)

Name Raul Cernuda

Job Title Firefighter

Address 2980 NW South River Drive

Phone 786-306-4719

Street

Miami

FL

33125

City

State

Zip

Email rcernuda@igff587.org

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing \_\_\_\_\_

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

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# APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/6/14

Meeting Date

SB 394

Bill Number (if applicable)

Topic Fire Safety

Amendment Barcode (if applicable)

Name Ryan Ventimiglia

Job Title Firefighter

Address 2980 NW S. River Dr

Phone 786 351 5872

Street

Miami

City

FL

State

33125

Zip

Email Crazeeryan@aol.com

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing \_\_\_\_\_

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

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# APPEARANCE RECORD

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2/6/18  
Meeting Date

SB 394  
Bill Number (if applicable)

Topic FIRE SAFETY

Amendment Barcode (if applicable)

Name DAN GIVEN'S

Job Title FIRE TRUSTER

Address 9941 SW 130 ST MIAMI  
Street

Phone 305 253 2442

MIAMI FL 33176  
City State Zip

Email DD GIVEN'S@BLLSOUTH.NET

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing \_\_\_\_\_

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

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# APPEARANCE RECORD

2/6/18

Meeting Date

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

SB 394

Bill Number (if applicable)

Topic Fire Safety

Amendment Barcode (if applicable)

Name John O'Brien

Job Title Firefighter

Address 2998 Virginia St

Phone 3) 389 7621

Street Miami State FL Zip 33133

Email j.o.brien29@gmail.com

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing \_\_\_\_\_

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

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# APPEARANCE RECORD

2/6/18

Meeting Date

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

SB 394

Bill Number (if applicable)

Topic Fire Safety

Amendment Barcode (if applicable)

Name DAVID PEREZ

Job Title Firefighter

Address 322 E 43 St

Phone 786-255-5791

Street Hialeah

City Hialeah State FL Zip 33013

Email

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against

(The Chair will read this information into the record.)

Representing Florida Professional firefighters IAFF Local 1210

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

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# APPEARANCE RECORD

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2/10/18  
Meeting Date

SB 394  
Bill Number (if applicable)

Topic Fire Safety

Amendment Barcode (if applicable)

Name Eric Johnson

Job Title Fire Captain

Address 752 East 1st Ave

Phone 3/970-8820

Hialeah FL 33010  
City State Zip

Email whitbe@aal.com

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing \_\_\_\_\_

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

*While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.*

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THE FLORIDA SENATE  
**APPEARANCE RECORD**

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/6/18

Meeting Date

SB399

Bill Number (if applicable)

Topic Fire Safety

Amendment Barcode (if applicable)

Name DAVID SHEPARD

Job Title Political Committee Chair

Address 6969 Venture Cir  
Street

Phone \_\_\_\_\_

ORLANDO  
City

State

32807  
Zip

Email dsheph1@y4k100.com

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing \_\_\_\_\_

Appearing at request of Chair:  Yes  No      Lobbyist registered with Legislature:  Yes  No

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**THE FLORIDA SENATE**  
**APPEARANCE RECORD**

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/6/18  
Meeting Date

SB 394  
Bill Number (if applicable)

Topic FIRE SAFETY

Amendment Barcode (if applicable)

Name LACRITA SWEENEY

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Street

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Orlando FL 32806  
City State Zip

Email msw@lcsweeney.com

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing OCFFA

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

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**THE FLORIDA SENATE**  
**APPEARANCE RECORD**

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/6/18  
Meeting Date

SB 394  
Bill Number (if applicable)

Topic Fire Safety

Amendment Barcode (if applicable)

Name Chris Ritchie

Job Title Treasurer

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Street

Phone 407 389 2057

Orlando FL 32827  
City State Zip

Email \_\_\_\_\_

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing \_\_\_\_\_

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

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THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/16/18

Meeting Date

3914

Bill Number (if applicable)

Topic Fire Safety

Amendment Barcode (if applicable)

Name Otto Drozd

Job Title Fire Chief Orange County Fire Rescue

Address 6590 AMORY COURT

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Street

Orlando FL

Email Otto.drozd@ocfl.net

City

State

Zip

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against (The Chair will read this information into the record.)

Representing Florida Fire Chiefs Association

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

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**THE FLORIDA SENATE**  
**APPEARANCE RECORD**

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/6/18  
Meeting Date

394  
Bill Number (if applicable)

Topic Fire Safety

~~925672~~  
Amendment Barcode (if applicable)  
on the bill

Name Jim Tolley

Job Title President Fla Prof Firefighters

Address 343 West Madison St Phone 850 224 7533  
Street

Tallahassee FL 32301 Email Jim@FPFP.org  
City State Zip

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing Florida Professional Firefighters

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

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S-001 (10/14/14)

THE FLORIDA SENATE  
**APPEARANCE RECORD**

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/6/18

Meeting Date

SB 394

Bill Number (if applicable)

Topic FIRE SAFETY

Amendment Barcode (if applicable)

Name RICHARD PIERCE

Job Title ~~1040 S. FL~~ FIRE FIGHTER

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Phone 321 323 6162

Street

ROCKLEDGE FL 32955

City

State

Zip

Email \_\_\_\_\_

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing BROWARD COUNTY FIRE FIGHTERS

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/6/18  
Meeting Date

SB 394  
Bill Number (if applicable)

Topic Fire Safety

Amendment Barcode (if applicable)

Name James Rucci

Job Title LEG. AFFAIRS LIASON

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Phone

Street

Port St Lucie FL 34986

Email

City

State

Zip

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing St Lucie Co Fire

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

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THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/6/18

Meeting Date

SB 394

Bill Number (if applicable)

Topic FIRE SAFETY

Amendment Barcode (if applicable)

Name KURT VROMAN

Job Title

Address 166 WILD WOOD DR

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Street

DEBARY

FL

32713

Email

City

State

Zip

Speaking: [X] For [ ] Against [ ] Information

Waive Speaking: [X] In Support [ ] Against (The Chair will read this information into the record.)

Representing DELTONA FIRE FIGHTER

Appearing at request of Chair: [ ] Yes [X] No

Lobbyist registered with Legislature: [X] Yes [ ] No

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THE FLORIDA SENATE  
**APPEARANCE RECORD**

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/6/18

Meeting Date

5B394

Bill Number (if applicable)

Topic FIRE SAFETY

Amendment Barcode (if applicable)

Name ANDRE PEREZ

Job Title PRESIDENT

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ORLANDO, FL 32807  
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Email Andreperes2@ocffa.com

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing ORANGE COUNTY FIRE FIGHTERS ASSOC

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

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**THE FLORIDA SENATE**  
**APPEARANCE RECORD**

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

1-6-10

Meeting Date

SB 374

Bill Number (if applicable)

Topic Fire Safety

Amendment Barcode (if applicable)

Name Eric Stend

Job Title Vice President

Address 6969 Venture Cr

Phone 4077389162

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Orl FL 32807

City

State

Zip

Email VicePresident@orange-fl.com

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing Orange County Firefighters Assoc

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

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S-001 (10/14/14)

THE FLORIDA SENATE  
**APPEARANCE RECORD**

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/6/18

Meeting Date

SB394

Bill Number (if applicable)

Topic Fire Safety

Amendment Barcode (if applicable)

Name Kevin Bellamy

Job Title \_\_\_\_\_

Address 5148 SE miles court tor

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Street

street

FL

34997

City

State

Zip

Email \_\_\_\_\_

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing St Lucie County Firefighters

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

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**THE FLORIDA SENATE**  
**APPEARANCE RECORD**

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/6/2018

Meeting Date

SB 394

Bill Number (if applicable)

Topic FIRE SAFETY

Amendment Barcode (if applicable)

Name ALBERT ROBERT

Job Title FIREFIGHTER

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FL

State

33125

Zip

Email ALBERTROBERT@LIVE.COM

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing \_\_\_\_\_

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

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S-001 (10/14/14)

**The Florida Senate**  
**BILL ANALYSIS AND FISCAL IMPACT STATEMENT**

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

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Prepared By: The Professional Staff of the Committee on Health Policy

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BILL: SB 524

INTRODUCER: Senator Brandes

SUBJECT: Influenza Virus and Streptococcal Infections

DATE: February 5, 2018

REVISED: \_\_\_\_\_

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto-Van Winkle	Stovall	HP	<b>Pre-meeting</b>
2.	_____	_____	AHS	_____
3.	_____	_____	AP	_____

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**I. Summary:**

SB 524 amends the definition of the practice of pharmacy to include testing for and treating the influenza virus and streptococcal infections. The bill authorizes a pharmacist to test and treat for the influenza virus and streptococcal infections within the framework of an established written protocol with a supervising physician. The Board of Pharmacy (board) is authorized to expand by rule on the minimum requirements for the protocol that are provided in the bill. A pharmacist must be certified pursuant to an approved certification program that includes at least eight hours of continuing education (CE) on specified subject matter to be eligible for this expanded practice.

**II. Present Situation:**

**The Practice of Professional Pharmacy**

Pharmacy is the third largest health care profession in the United States behind nursing and medicine.<sup>1</sup> The board, in conjunction with the Department of Health (DOH), regulates the practice of pharmacists pursuant to ch. 465, F.S.<sup>2</sup>

The scope of “practice of the profession of pharmacy” includes:

- Compounding, dispensing, and consulting concerning the contents, therapeutic values, and uses of any medicinal drug;
- The administration of vaccines to adults;<sup>3</sup> and
- Other pharmaceutical services.<sup>4</sup>

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<sup>1</sup> American Association of Colleges of Pharmacy, *About AACP*, <https://www.aacp.org/about-aacp> (last visited Jan. 31, 2018).

<sup>2</sup> Sections 465.004 and 465.005, F.S.

<sup>3</sup> See s. 465.189, F.S.

<sup>4</sup> Section 465.003(13), F.S.

The term “other pharmaceutical services” includes:

- Monitoring a patient’s drug therapy;
- Assisting a patient with drug therapy management;
- Reviewing a patient’s drug therapy;
- Communicating with a patient’s prescribing health care practitioner; and
- Any other act, service, operation, research, or transaction incidental to any branch of the pharmaceutical profession.<sup>5</sup>

Pharmacists are specifically prohibited from altering a prescriber’s directions, diagnoses or treatment plan, initiating any drug therapy, and practicing medicine, unless permitted by law.<sup>6</sup>

To be licensed as a pharmacist in Florida, a person must:

- Be at least 18 years of age;
- Hold a degree from an accredited and approved school or college of pharmacy;<sup>7</sup>
- Have completed a board-approved internship; and
- Obtain a passing score on the board-approved examination.<sup>8</sup>

A pharmacist must complete at least 30 hours of continuing education (CE) for each biennial license renewal period.<sup>9</sup> A pharmacist who is certified to administer vaccines or epinephrine autoinjections must complete three hours of CE on the safe and effective administration of vaccines and epinephrine injections as a part of his or her licensure renewal. This three hours of CE is included within the 30-hour requirement for licensure renewal.<sup>10</sup>

### ***Pharmacist Administration of Vaccines and Injections***

A pharmacist may become certified to administer the immunizations or vaccines listed in the Centers for Disease Prevention and Control (CDC) Adult Immunization Schedule as of February 1, 2015, as well as those recommended for international travel as of July 1, 2015.<sup>11</sup>

To be certified to administer vaccines, a pharmacist must:

- Enter into a written protocol with a supervising physician which is filed with the board. The protocol must include:<sup>12</sup>
  - The categories and conditions of patients to whom the pharmacist may administer vaccines;

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<sup>5</sup> *Id.*

<sup>6</sup> Section 464.003(13), F.S.

<sup>7</sup> Section 465.007(1)(b)2., F.S. If the applicant has graduated from a four year undergraduate pharmacy program of a school or college of pharmacy located outside the United States, the applicant must demonstrate proficiency in English, pass the board-approved Foreign Pharmacy Graduate Equivalency Examination, and complete a minimum of 500 hours in a supervised work activity program within Florida under the supervision of a DOH-licensed pharmacist.

<sup>8</sup> The DOH may also issue a license by endorsement to a pharmacist who is licensed in another state upon meeting the applicable requirements set forth in law and rule. *See* s. 465.0075, F.S.

<sup>9</sup> Section 465.009, F.S.

<sup>10</sup> Section 465.009(6), F.S.

<sup>11</sup> Section 465.189, F.S., A registered intern may also administer immunizations or vaccines under the supervision of a certified pharmacist.

<sup>12</sup> Section 465.189(1) and (7), F.S.

- Terms, scope and conditions that are appropriate to the pharmacist's training and certification; and
- The process and schedule for the review of the administration of vaccines by the supervising physician pursuant to the written protocol.
- Complete a board-approved vaccine administration certification program that consists of at least 20 hours of CE, and provide evidence of this to the supervising physician;<sup>13</sup>
- Demonstrate vaccine administration techniques;<sup>14</sup> and
- Maintain at least \$200,000 of professional liability insurance.<sup>15</sup>

A pharmacist may also administer epinephrine using an autoinjector delivery system, within a protocol with the supervising physician to treat any allergic reactions resulting from a vaccine.<sup>16</sup> A pharmacist administering vaccines must provide the DOH with a patient's vaccination records for inclusion in the state's immunization registry.<sup>17</sup>

### ***Pharmacist Administration of Antipsychotic Medication by Injection***

In 2017, the Legislature authorized a licensed pharmacist to administer an injection of a long-acting antipsychotic medication<sup>18</sup> approved by the United States Food and Drug Administration.<sup>19</sup> To be eligible to administer such injections, a pharmacist must:<sup>20</sup>

- Be authorized in a protocol with the prescribing physician;
- Practice at a facility that accommodates privacy for non-deltoid injections and provides for safe disposal of medications and medical waste;<sup>21</sup> and
- Complete eight hours of CE on the safe and effective administration of behavioral health and antipsychotic medications by injection, including potential allergic reactions.

A separate prescription from a physician is required for each injection administered.

### **Diagnostic Tests for Influenza and Streptococcus**

#### ***Influenza Tests***

Influenza is a viral, contagious respiratory illness.<sup>22</sup> Although the influenza virus may be detected at any time of the year, the influenza virus is most common during the fall and winter.<sup>23</sup>

<sup>13</sup> Section 465.189(6), F.S., and Rule 64B16-26.1031, F.A.C., provides more detail regarding subject matter that must be included in the certification course.

<sup>14</sup> Section 465.189(3), F.S.

<sup>15</sup> *Id.*

<sup>16</sup> Section 465.189(2), F.S.

<sup>17</sup> Section 465.189(5), F.S.

<sup>18</sup> A long-acting injectable antipsychotic medication may be prescribed to treat symptoms of psychosis associated with schizophrenia and schizoaffective disorder and provided once or twice a month. It may be prescribed for individuals who have difficulty remembering to take daily medications or who have a history of discontinuing medication. National Alliance on Mental Illness, *Mental Health Medications* (August 2017) available at <https://www.nami.org/Learn-More/Treatment/Mental-Health-Medications> (last visited Jan. 31, 2018).

<sup>19</sup> Section 465.1893, F.S.

<sup>20</sup> *Id.*

<sup>21</sup> Section 381.0098, F.S., and Rule 64E-16, F.A.C., regulate the disposal of biomedical waste.

<sup>22</sup> U.S. Department of Health and Human Services, Center for Disease Control and Prevention, *About Flu*, (Oct. 5, 2017), available at <https://www.cdc.gov/flu/about/index.html> (last visited Jan. 31, 2018).

<sup>23</sup> *Id.*

Each year, on average 5 to 20 percent of the United States population gets the influenza, tens of thousands are hospitalized, and thousands die from influenza related illnesses.<sup>24</sup> It is estimated that the influenza results in \$10.4 billion in direct medical expenses and an additional \$16.3 billion in lost earnings annually.<sup>25</sup>

A person who has contracted the influenza virus is typically contagious for the first three to four days after the illness begins.<sup>26</sup> However, some individuals may be able to infect others beginning one day before symptoms develop and up to five to seven days after becoming sick.<sup>27</sup> According to the CDC, most people infected with influenza will have a mild illness and do not need medical care or antiviral medication.<sup>28</sup> However, the CDC advises individuals who develop influenza symptoms and are at higher risk of complications to contact a health care practitioner as early as possible to begin antiviral treatment.<sup>29</sup> The CDC recommends an annual vaccination as the best way to prevent influenza.<sup>30</sup>

Individuals with weakened immune systems, the elderly, young children, or those with certain health conditions, may be at high risk of serious flu complications.<sup>31</sup> Complications of influenza may include bacterial pneumonia, ear infections, sinus infections, and worsening of chronic medical conditions, such as congestive heart failure, asthma, or diabetes.<sup>32</sup> Serious influenza infections can result in hospitalizations or death.

In recent years, the Food and Drug Administration has approved more than 10 rapid influenza diagnostic tests (RIDTs) to screen for influenza virus infection.<sup>33</sup> These tests can provide results within approximately 15 minutes and may be used to help with diagnosis and treatment decisions for patients.<sup>34</sup> However, a variety of factors can influence the accuracy of an RIDT, including the type of specimen tested, whether the specimen is collected within 72 hours of the onset of the illness, and the prevalence of flu activity in the area.<sup>35</sup> False positive results are more likely at the beginning or end of the influenza season or during periods when the flu virus is not circulating, such as the summer. False negative results are more likely at the peak of the influenza season.<sup>36</sup>

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<sup>24</sup> U.S. Department of Health and Human Services, Center for Disease Control and Prevention, Foundation, *Flu Prevention*, available at <https://www.cdcfoundation.org/businesspulse/flu-prevention-infographic> (last visited Jan. 31, 2018).

<sup>25</sup> *Id.*

<sup>26</sup> U.S. Department of Health and Human Services, Center for Disease Control and Prevention, *Key Facts about Influenza (Flu)*, (Oct. 5, 2017), available at <https://www.cdc.gov/flu/keyfacts.htm> (last visited Jan. 31, 2018).

<sup>27</sup> *Id.*

<sup>28</sup> U.S. Department of Health and Human Services, Center for Disease Control and Prevention, *The Flu: What to Do if You Get Sick*, (Feb. 14, 2017), available at <https://www.cdc.gov/flu/takingcare.htm> (last visited Jan. 31, 2018).

<sup>29</sup> *Id.*

<sup>30</sup> *Id.*

<sup>31</sup> *Supra* note 22.

<sup>32</sup> *Supra* note 29.

<sup>33</sup> U.S. Department of Health and Human Services, Center for Disease Control and Prevention, *Rapid Diagnostic Testing for Influenza: Information for Clinical Laboratory Directors*, (Oct. 26, 2016), available at <https://www.cdc.gov/flu/professionals/diagnosis/rapidlab.htm> (last visited Jan. 31, 2018).

<sup>34</sup> *Id.*

<sup>35</sup> U.S. Department of Health and Human Services, Center for Disease Control and Prevention, *Guidance for Clinicians on the Use of Rapid Influenza Diagnostic Tests*, [https://www.cdc.gov/flu/pdf/professionals/diagnosis/clinician\\_guidance\\_ridt.pdf](https://www.cdc.gov/flu/pdf/professionals/diagnosis/clinician_guidance_ridt.pdf) (last visited Jan. 31, 2018).

<sup>36</sup> *Id.*

A health care practitioner may diagnose an individual with influenza based on symptoms and his or her clinical judgment, irrespective of the test results.<sup>37</sup>

Some pharmacies may currently provide influenza testing, as well as other health screenings.<sup>38</sup> However, these pharmacies vary by the types of patients seen, the array of services offered, the type of health care practitioner available, and the type of medications prescribed.

### ***Streptococcus Testing***

Streptococcus (Strep) is a bacteria that causes a variety of infections. There are two types of Strep. Group A Strep infections include Strep throat, scarlet fever, impetigo, toxic shock syndrome and cellulitis and necrotizing fasciitis.<sup>39</sup> Group B Strep may cause blood infections, pneumonia, and meningitis in newborns, as well as urinary tract infections, blood infections, skin infections, and pneumonia in adults.<sup>40</sup> Strep throat, along with minor skin infections, are the most common infection.<sup>41</sup>

Strep throat is a highly contagious Group A strep infection. It is most common in children between ages 5 and 15; however, anyone may contract it.<sup>42</sup> Strep throat is passed through person to person contact. A person who has been treated with antibiotics for 24 hours or longer however, can generally no longer transmit the bacteria.<sup>43</sup> If Strep throat is not diagnosed and treated, it may lead to complications such as rheumatic fever, which can damage the heart, or glomerulonephritis, which affects the kidney.<sup>44</sup>

Rapid antigen diagnostic tests (RADTs) may be used to determine the presence of Group A Strep in a patient's throat or other infected areas.<sup>45</sup> Results are generally available within ten to 20 minutes; however, some tests may be able to detect the presence of Group A Strep bacteria

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<sup>37</sup> U.S. Department of Health and Human Services, Center for Disease Control and Prevention, *Diagnosing Flu: Questions and Answers*, (Oct. 3, 2017), available at <https://www.cdc.gov/flu/about/qa/testing.htm> (last visited Jan. 31, 2018).

<sup>38</sup> Examples are: CVS Pharmacy offers services through its MinuteClinic®, which is staffed by nurse practitioners or physician assistants (*see* CVS, *Want to Learn More about MinuteClinic®*, available at <https://www.cvs.com/minuteclinic/services/minor-illnesses/flu-like-symptoms/N-d8ZbtmkZd5> (last visited Jan. 31, 2018); Walgreens offers services through its Healthcare Clinic, which is staffed by professional healthcare professionals (*see* Walgreens, *Healthcare Clinic*, available at <https://www.walgreens.com/topic/pharmacy/healthcare-clinic.jsp> (last visited Jan. 31, 2018); Walmart offers services through *Walmart Care Clinics* which are staffed by ARNPs available at: <https://www.walmart.com/cp/care-clinics/1224932> (last visited Jan. 31, 2018).

<sup>39</sup> U.S. National Library of Medicine, Medline Plus, *Streptococcal Infections*, (Oct. 3, 2017), available at <https://medlineplus.gov/streptococcalinfections.html> (last visited Jan. 31, 2018).

<sup>40</sup> *Id.*

<sup>41</sup> National Institute of Allergy and Infectious Diseases, *Group A Streptococcal Infections*, (last rev. Sept. 29, 2015), available at <https://www.niaid.nih.gov/diseases-conditions/group-streptococcal-infections> (last visited Jan. 31, 2018).

<sup>42</sup> *Supra* note 39.

<sup>43</sup> U.S. Department of Health and Human Services, Center for Disease Control and Prevention, *Pharyngitis (Strep Throat)*, (Sept. 16, 2016), available at <https://www.cdc.gov/groupastrep/diseases-hcp/strep-throat.html#resources> (last visited Jan. 31, 2018).

<sup>44</sup> U.S. Department of Health and Human Services, Center for Disease Control and Prevention, *Strep Throat*, available at <https://www.cdc.gov/groupastrep/diseases-public/strep-throat.html#complications> (last visited Feb. 2, 2018).

<sup>45</sup> John Mersch, MD, FAAP *Rapid Strep Test*, MedicineNet.Com (Aug. 23, 2016), [https://www.medicinenet.com/rapid\\_strep\\_test/article.htm](https://www.medicinenet.com/rapid_strep_test/article.htm) (last visited Jan. 31, 2018).



within eight minutes.<sup>46</sup> RADTs, in general, have high diagnostic accuracy, with tests using newer techniques providing the greatest accuracy.<sup>47</sup>

### III. Effect of Proposed Changes:

The bill amends the definition of the practice of the profession of pharmacy to expand the scope of practice for pharmacists to include testing for and treating influenza virus and streptococcal infections.

The bill creates s. 465.1895, F.S., to authorize a pharmacist to test and treat for the influenza virus and streptococcal infections within an established written protocol with a supervising physician licensed under chs. 458 or 459, F.S. Additionally, to be eligible to provide these services a pharmacist must:

- Complete an eight hour certification course approved by the board, in consultation with the Board of Medicine and the Board of Osteopathic Medicine, with curriculum concerning point-of-care testing for the influenza virus and streptococcal infections and the safe and effective treatment of the influenza virus and streptococcal infections;
- Maintain at least \$200,000 of professional liability insurance;
- Maintain, and make available, patient records for five years; and
- Obtain written approval of the pharmacy owner, if the pharmacist is acting as an employee of the pharmacy.

The bill provides that a supervising physician's decision to enter into a written protocol under this section is a professional decision and a person may not interfere with the physician's decision.

The bill authorizes the board to adopt rules establishing the requirements of the written protocol. The protocol must include:

- Any terms and conditions imposed by the supervising physician relating to testing for and treating the influenza virus and streptococcal infections;
- Appropriate terms and conditions relative to the pharmacist's training;
- Specific categories of patients that the supervising physician authorizes the pharmacist to test and treat;
- The supervising physician's instructions for the treatment of the influenza virus and streptococcal infections based on a patient's age, symptoms, and test results, including negative results;
- A process and schedule for the supervising physician to review the pharmacist's patient interactions and treatment;
- A process and schedule for the pharmacist to notify the supervising physician of a patient's condition, tests administered, test results, and course of treatment; and
- A process and schedule for the supervising physician to review the pharmacist's administration of vaccines.

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<sup>46</sup> *Supra* note 44.

<sup>47</sup> W. L. Lean et al., *Rapid Diagnostic Tests for Group A Streptococcal Pharyngitis: A Meta-analysis*, PEDIATRICS Volume 134, Number 4, October 2014 available at

<http://pediatrics.aappublications.org/content/pediatrics/early/2014/09/02/peds.2014-1094.full.pdf> (last visited Jan. 31, 2018).

The bill requires the supervising physician to review the pharmacist's action.

Pharmacists who have been delegated the authority to test for and treat the influenza virus and streptococcal infections by a supervising physician must provide that physician with evidence of a current certification from the board.

The bill takes effect July 1, 2018.

**IV. Constitutional Issues:**

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

**V. Fiscal Impact Statement:**

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Authorizing pharmacists to test and treat for the influenza virus and streptococcal infections might reduce the time from the occurrence of symptoms to treatment; and may reduce the cost to patients for obtaining these services without a doctor's office or emergency room visit.

Pharmacies may also experience increased revenue from this additional service.

C. Government Sector Impact:

The DOH may incur costs associated with requiring the board to approve certification programs, in consultation with the BOM and BOOM; and in adopting rules to establish the requirements for the written protocol between the pharmacist and supervising physician.

The DOH may experience a recurring increase in workload associated with the submission of written protocols between the pharmacists and supervising physician.

**VI. Technical Deficiencies:**

None.

**VII. Related Issues:**

The bill is silent regarding whether the eight hours of CE for the certification program may be part of the 30 hours of CE required for biennial license renewal. No ongoing CE is required. The authority to administer vaccines and epinephrine includes 20 hours of CE for certification and three hours for CE for each license renewal period.

**VIII. Statutes Affected:**

This bill substantially amends section 465.003, of the Florida Statutes.

This bill creates section 465.1895 of the Florida Statutes.

**IX. Additional Information:****A. Committee Substitute – Statement of Changes:**

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

**B. Amendments:**

None.



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LEGISLATIVE ACTION

Senate	.	House
Comm: FAV	.	
02/06/2018	.	
	.	
	.	
	.	

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The Committee on Health Policy (Brandes) recommended the following:

**Senate Amendment (with title amendment)**

Delete everything after the enacting clause  
and insert:

Section 1. Subsection (2) of section 381.0031, Florida  
Statutes, is amended to read:

381.0031 Epidemiological research; report of diseases of  
public health significance to department.—

(2) Any practitioner licensed in this state to practice  
medicine, osteopathic medicine, chiropractic medicine,



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11 naturopathy, or veterinary medicine; any licensed pharmacist  
12 authorized pursuant to a protocol to order and evaluate  
13 laboratory and clinical tests; any hospital licensed under part  
14 I of chapter 395; or any laboratory licensed under chapter 483  
15 that diagnoses or suspects the existence of a disease of public  
16 health significance shall immediately report the fact to the  
17 Department of Health.

18 Section 2. Subsection (13) of section 465.003, Florida  
19 Statutes, is amended to read:

20 465.003 Definitions.—As used in this chapter, the term:

21 (13) "Practice of the profession of pharmacy" includes  
22 compounding, dispensing, and consulting concerning contents,  
23 therapeutic values, and uses of any medicinal drug; consulting  
24 concerning therapeutic values and interactions of patent or  
25 proprietary preparations, whether pursuant to prescriptions or  
26 in the absence and entirely independent of such prescriptions or  
27 orders; and other pharmaceutical services. For purposes of this  
28 subsection, "other pharmaceutical services" means the monitoring  
29 of the patient's drug therapy and assisting the patient in the  
30 management of his or her drug therapy, and includes review of  
31 the patient's drug therapy and communication with the patient's  
32 prescribing health care provider as licensed under chapter 458,  
33 chapter 459, chapter 461, or chapter 466, or similar statutory  
34 provision in another jurisdiction, or such provider's agent or  
35 such other persons as specifically authorized by the patient,  
36 regarding the drug therapy. However, ~~nothing in~~ this subsection  
37 may not be interpreted to permit an alteration of a prescriber's  
38 directions, the diagnosis or treatment of any disease, the  
39 initiation of any drug therapy, the practice of medicine, or the



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40 practice of osteopathic medicine, unless otherwise permitted by  
41 law. The term "Practice of the profession of pharmacy" also  
42 includes any other act, service, operation, research, or  
43 transaction incidental to, or forming a part of, any of the  
44 foregoing acts, requiring, involving, or employing the science  
45 or art of any branch of the pharmaceutical profession, study, or  
46 training, and shall expressly permit a pharmacist to transmit  
47 information from persons authorized to prescribe medicinal drugs  
48 to their patients. The term practice of the profession of  
49 pharmacy also includes the administration of vaccines to adults  
50 pursuant to s. 465.189 and testing for and treating influenza  
51 pursuant to s. 465.1895.

52 Section 3. Section 465.1895, Florida Statutes, is created  
53 to read:

54 465.1895 Testing for and treating influenza.—

55 (1) A pharmacist may test for and treat influenza within  
56 the framework of an established written protocol under a  
57 supervising physician who is licensed under chapter 458 or  
58 chapter 459 if all of the following criteria are met:

59 (a) The pharmacist uses a test that the federal Centers for  
60 Medicare and Medicaid Services have determined qualifies for a  
61 certificate of waiver under the federal Clinical Laboratory  
62 Improvement Amendments of 1988, and the federal rules adopted  
63 thereunder.

64 (b) The pharmacist uses a test system that integrates with  
65 certified electronic health record technology as defined in s.  
66 408.051.

67 (c) The pharmacist submits test results to a health care  
68 practitioner designated by the patient.



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69       (d) The pharmacist reports a diagnosis or suspected  
70 existence of a disease of public health significance to the  
71 department as required under s. 381.0031.

72       (2) A pharmacist may only enter into a protocol under this  
73 section if he or she maintains at least \$200,000 of professional  
74 liability insurance and has completed the training required by  
75 this section.

76       (3) A pharmacist testing for and treating influenza shall  
77 maintain and make available patient records using the same  
78 standards for confidentiality and maintenance of such records as  
79 those that are imposed on health care practitioners under s.  
80 456.057. These records must be maintained for a minimum of 5  
81 years.

82       (4) A supervising physician's decision to enter into a  
83 protocol under this section is a professional decision and a  
84 person may not interfere with a supervising physician's decision  
85 to enter into such a protocol. A pharmacist may not perform a  
86 protocol while acting as a pharmacy employee without the written  
87 approval of the pharmacy owner.

88       (5) Any pharmacist seeking to test for and treat influenza  
89 under this section must be certified to do so pursuant to a  
90 certification program approved by the board in consultation with  
91 the Board of Medicine and the Board of Osteopathic Medicine. The  
92 certification program must, at a minimum, require that the  
93 pharmacist attend at least 8 hours of continuing education  
94 classes approved by the board. The program must have a  
95 curriculum of instruction concerning, at a minimum, point-of-  
96 care testing for influenza and the safe and effective treatment  
97 of influenza.



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98           (6) The board may adopt rules establishing the requirements  
99 for a protocol between a pharmacist and a supervising physician.  
100 The protocol must be in writing and, at a minimum, must include  
101 all of the following:

102           (a) Any terms and conditions imposed by the supervising  
103 physician relating to testing for and treating influenza  
104 pursuant to this section. The terms and conditions set forth in  
105 the protocol must be appropriate to the pharmacist's training.

106           (b) Specific categories of patients for whom the  
107 supervising physician authorizes the pharmacist to test for and  
108 treat influenza.

109           (c) The supervising physician's instructions for the  
110 treatment of influenza based on the patient's age, symptoms, and  
111 test results, including negative results.

112           (d) A process and schedule for the supervising physician to  
113 review the pharmacist's actions under the protocol.

114           (e) A process and schedule for the pharmacist to notify the  
115 supervising physician of the patient's condition, tests  
116 administered, test results, and course of treatment.

117           (7) Pharmacists who have been delegated the authority to  
118 test for and treat influenza by a supervising physician shall  
119 provide the supervising physician with evidence of current  
120 certification by the board. A supervising physician shall review  
121 the pharmacist's actions pursuant to the protocol in effect, and  
122 this review shall take place as outlined in the protocol.

123           (8) The pharmacist shall submit to the board a copy of his  
124 or her protocol to test for and treat influenza.

125           Section 4. This act shall take effect upon becoming a law.  
126





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127 ===== T I T L E A M E N D M E N T =====

128 And the title is amended as follows:

129 Delete everything before the enacting clause

130 and insert:

131 A bill to be entitled

132 An act relating to the testing for and treatment of  
133 influenza; amending s. 381.0031, F.S.; requiring  
134 certain licensed pharmacists to report certain  
135 information to the Department of Health; amending s.  
136 465.003, F.S.; expanding the definition of the term  
137 "practice of the profession of pharmacy" to include  
138 testing for and treating influenza; creating s.  
139 465.1895, F.S.; authorizing a pharmacist to test for  
140 and treat influenza within the framework of an  
141 established written protocol under a supervising  
142 physician if certain requirements are met; requiring a  
143 pharmacist testing for and treating influenza to  
144 maintain patient records using certain standards and  
145 for a specified time; prohibiting a person from  
146 interfering with a supervising physician's decision to  
147 enter into a protocol; prohibiting a pharmacist from  
148 performing a protocol while acting as a pharmacy  
149 employee without the written approval of the pharmacy  
150 owner; requiring a pharmacist seeking to test for and  
151 treat influenza to be certified by a certification  
152 program approved by the Board of Pharmacy in  
153 consultation with the Board of Medicine and the Board  
154 of Osteopathic Medicine; providing criteria for  
155 certification programs; authorizing the Board of



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156 Pharmacy to adopt rules establishing the requirements  
157 for a protocol; requiring that the protocol be in  
158 writing and contain certain information, terms, and  
159 conditions; requiring that pharmacists authorized to  
160 test for and treat influenza provide their supervising  
161 physician with evidence of current certification by  
162 the board; requiring a supervising physician to review  
163 the pharmacist's actions; requiring a pharmacist to  
164 submit his or her protocol to the board; providing an  
165 effective date.

By Senator Brandes

24-00564-18

2018524\_\_

1                                   A bill to be entitled  
2       An act relating to the influenza virus and  
3       streptococcal infections; amending s. 465.003, F.S.;  
4       expanding the definition of the term "practice of the  
5       profession of pharmacy" to include testing for and  
6       treating the influenza virus and streptococcal  
7       infections; creating s. 465.1895, F.S.; authorizing  
8       pharmacists to test for and treat the influenza virus  
9       and streptococcal infections within the framework of  
10      an established written protocol under a supervising  
11      physician under certain conditions; requiring a  
12      pharmacist testing for and treating the influenza  
13      virus and streptococcal infections to maintain patient  
14      records using certain standards and for a specified  
15      time; prohibiting a person from interfering with a  
16      supervising physician's decision to enter into a  
17      protocol; prohibiting a pharmacist from performing a  
18      protocol while acting as a pharmacy employee without  
19      the written approval of the pharmacy owner; requiring  
20      a pharmacist seeking to test for and treat the  
21      influenza virus and streptococcal infections to obtain  
22      certification through a certification program approved  
23      by the Board of Pharmacy in consultation with the  
24      Board of Medicine and the Board of Osteopathic  
25      Medicine; providing criteria for certification  
26      programs; authorizing the Board of Pharmacy to adopt  
27      rules establishing the requirements for a protocol;  
28      requiring that the protocol be in writing and contain  
29      certain information, terms, and conditions; requiring

24-00564-18

2018524\_\_

30 that pharmacists authorized to test for and treat the  
31 influenza virus and streptococcal infections provide  
32 their supervising physician with evidence of current  
33 certification by the board; requiring a supervising  
34 physician to review the pharmacist's actions;  
35 requiring a pharmacist to submit his or her protocol  
36 to the board; providing an effective date.  
37

38 Be It Enacted by the Legislature of the State of Florida:  
39

40 Section 1. Subsection (13) of section 465.003, Florida  
41 Statutes, is amended to read:

42 465.003 Definitions.—As used in this chapter, the term:  
43 (13) "Practice of the profession of pharmacy" includes  
44 compounding, dispensing, and consulting concerning contents,  
45 therapeutic values, and uses of any medicinal drug; consulting  
46 concerning therapeutic values and interactions of patent or  
47 proprietary preparations, whether pursuant to prescriptions or  
48 in the absence and entirely independent of such prescriptions or  
49 orders; and other pharmaceutical services. For purposes of this  
50 subsection, "other pharmaceutical services" means the monitoring  
51 of the patient's drug therapy and assisting the patient in the  
52 management of his or her drug therapy, and includes review of  
53 the patient's drug therapy and communication with the patient's  
54 prescribing health care provider as licensed under chapter 458,  
55 chapter 459, chapter 461, or chapter 466, or similar statutory  
56 provision in another jurisdiction, or such provider's agent or  
57 such other persons as specifically authorized by the patient,  
58 regarding the drug therapy. However, ~~nothing in~~ this subsection

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2018524\_\_

59 may not be interpreted to permit an alteration of a prescriber's  
60 directions, the diagnosis or treatment of any disease, the  
61 initiation of any drug therapy, the practice of medicine, or the  
62 practice of osteopathic medicine, unless otherwise permitted by  
63 law. The term "Practice of the profession of pharmacy" also  
64 includes any other act, service, operation, research, or  
65 transaction incidental to, or forming a part of, any of the  
66 foregoing acts, requiring, involving, or employing the science  
67 or art of any branch of the pharmaceutical profession, study, or  
68 training, and shall expressly permit a pharmacist to transmit  
69 information from persons authorized to prescribe medicinal drugs  
70 to their patients. The practice of the profession of pharmacy  
71 also includes the administration of vaccines to adults pursuant  
72 to s. 465.189 and testing for and treating the influenza virus  
73 and streptococcal infections pursuant to s. 465.1895.

74 Section 2. Section 465.1895, Florida Statutes, is created  
75 to read:

76 465.1895 Testing for and treating influenza and  
77 streptococcal infections.-

78 (1) A pharmacist may test for and treat the influenza virus  
79 and streptococcal infections within the framework of an  
80 established written protocol under a supervising physician who  
81 is licensed under chapter 458 or chapter 459.

82 (2) A pharmacist may only enter into a protocol under this  
83 section if he or she maintains at least \$200,000 of professional  
84 liability insurance and has completed the training required by  
85 this section.

86 (3) A pharmacist testing for and treating the influenza  
87 virus and streptococcal infections shall maintain and make

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2018524\_\_

88 available patient records using the same standards for  
89 confidentiality and maintenance of such records as required  
90 pursuant to s. 456.057. These records must be maintained for a  
91 minimum of 5 years.

92 (4) A supervising physician's decision to enter into a  
93 protocol under this section is a professional decision and a  
94 person may not interfere with a supervising physician's decision  
95 to enter into such a protocol. A pharmacist may not perform a  
96 protocol while acting as a pharmacy employee without the written  
97 approval of the pharmacy owner.

98 (5) Any pharmacist seeking to test for and treat the  
99 influenza virus and streptococcal infections under this section  
100 must be certified to do so pursuant to a certification program  
101 approved by the board in consultation with the Board of Medicine  
102 and the Board of Osteopathic Medicine. The certification program  
103 must, at a minimum, require that the pharmacist attend at least  
104 8 hours of continuing education classes approved by the board.  
105 The program must have a curriculum of instruction concerning, at  
106 a minimum, point-of-care testing for the influenza virus and  
107 streptococcal infections and the safe and effective treatment of  
108 the influenza virus and streptococcal infections.

109 (6) The board may adopt rules establishing the requirements  
110 for a protocol between a pharmacist and supervising physician.  
111 The protocol must be in writing and, at a minimum, must include  
112 all of the following:

113 (a) Any terms and conditions imposed by the supervising  
114 physician relating to testing for and treating the influenza  
115 virus and streptococcal infections pursuant to this section. The  
116 terms and conditions set forth in the protocol must be

24-00564-18

2018524\_\_

117 appropriate to the pharmacist's training.

118 (b) Specific categories of patients for whom the  
119 supervising physician authorizes the pharmacist to test for and  
120 treat the influenza virus and streptococcal infections.

121 (c) The supervising physician's instructions for the  
122 treatment of the influenza virus and streptococcal infections  
123 based on the patient's age, symptoms, and test results,  
124 including negative results.

125 (d) A process and schedule for the supervising physician to  
126 review the pharmacist's actions under the protocol.

127 (e) A process and schedule for the pharmacist to notify the  
128 supervising physician of the patient's condition, tests  
129 administered, test results, and course of treatment.

130 (7) Pharmacists who have been delegated the authority to  
131 test for and treat the influenza virus and streptococcal  
132 infections by a supervising physician shall provide the  
133 supervising physician with evidence of current certification by  
134 the board. A supervising physician shall review the pharmacist's  
135 actions pursuant to the protocol in effect, and this review  
136 shall take place as outlined in the protocol.

137 (8) The pharmacist shall submit to the board a copy of his  
138 or her protocol to test for and treat the influenza virus and  
139 streptococcal infections.

140 Section 3. This act shall take effect July 1, 2018.



The Florida Senate

## Committee Agenda Request

**To:** Senator Dana D. Young  
Committee on Health Policy

**Subject:** Committee Agenda Request

**Date:** November 3, 2017

---

I respectfully request that **Senate Bill #524**, relating to **Influenza Virus and Streptococcal Infections**, be placed on the:

- committee agenda at your earliest possible convenience.
- next committee agenda.

A handwritten signature in black ink, appearing to read "Jeff Brandes", written over a horizontal line.

Senator Jeff Brandes  
Florida Senate, District 24



**THE FLORIDA SENATE**  
**APPEARANCE RECORD**

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/6/2018  
Meeting Date

SB524  
Bill Number (if applicable)  
788828  
Amendment Barcode (if applicable)

Topic INFLUENZA VIRUS AND STREPTOCOCCUS INFECTIONS

Name MICHAEL A. JACKSON

Job Title EXECUTIVE VICE PRESIDENT AND CEO

Address 610 N. ADAMS STREET

Phone 850 222-2400

TALLAHASSEE FLORIDA 32301  
City State Zip

Email MJACKSON@PHARMVIEW.COM

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
*(The Chair will read this information into the record.)*

Representing FLORIDA PHARMACY ASSOCIATION

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

*While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.*

**This form is part of the public record for this meeting.**

**THE FLORIDA SENATE**  
**APPEARANCE RECORD**

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/6/2018

*Meeting Date*

SB524

*Bill Number (if applicable)*

Topic Influenza Virus and Streptococcus Infections

*Amendment Barcode (if applicable)*

Name Michael A. Jackson

Job Title Executive Vice President and CEO

Address 610 North Adams Street

Phone (850) 222-2400

*Street*

Tallahassee

Florida

32301

Email mjackson@pharmview.com

*City*

*State*

*Zip*

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
*(The Chair will read this information into the record.)*

Representing Florida Pharmacy Association

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

*While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.*

***This form is part of the public record for this meeting.***

S-001 (10/14/14)

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/6/2018

Meeting Date

SB 524

Bill Number (if applicable)

Topic Influenza Virus & Streptococcal Infections

Amendment Barcode (if applicable)

Name Bill Minley

Job Title VP PPSC

Address 3375 Capital Circle NE Suite I

Phone 850-553-3595

Street

Tallahassee, FL

State

32308

Zip

Email bill.minley@ppsconline.com

Speaking: [ ] For [ ] Against [ ] Information

Waive Speaking: [x] In Support [ ] Against (The Chair will read this information into the record.)

Representing PPSC-FIPN Small Business Pharmacy Owners

Appearing at request of Chair: [ ] Yes [x] No

Lobbyist registered with Legislature: [ ] Yes [x] No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/6/18

Meeting Date

524

Bill Number (if applicable)

Topic \_\_\_\_\_

Amendment Barcode (if applicable)

Name Chris Nuland

Job Title \_\_\_\_\_

Address 1000 Riverside Ave #240

Phone 904-233-3051

Street

Jacksonville, FL 32204

Email nulandlaw@aol.com

City

State

Zip

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing Florida Chapter, American College of Physicians

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

**THE FLORIDA SENATE**  
**APPEARANCE RECORD**

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

SB524

Bill Number (if applicable)

Meeting Date

Amendment Barcode (if applicable)

Topic Test + Treat

Name Griff C Danheim

Job Title Director Specialty Markets

Address 12544 High Bluff Dr. Ste 200

Phone 713-560-0047

City San Diego State CA Zip 92130

Email griff.danheim@quidel.com

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing Quidel Corp

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

**THE FLORIDA SENATE**  
**APPEARANCE RECORD**

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/6/18

Meeting Date

SB 524

Bill Number (if applicable)

Topic \_\_\_\_\_

Amendment Barcode (if applicable)

Name Michael Forsthoefel, MD

Job Title \_\_\_\_\_

Address 1430 Piedmont Dr. E.

Phone 850 ~~251-24~~ 224-6496

Street

Tallahassee

FL

32308

Email \_\_\_\_\_

City

State

Zip

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing Florida Medical Association

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

**This form is part of the public record for this meeting.**

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/6/18

Meeting Date

524

Bill Number (if applicable)

Topic Flu/Strep

Amendment Barcode (if applicable)

Name Stephen Winn

Job Title Executive Director

Address 2544 Blairstone Pines Dr

Phone 878-3056

Street

Tallahassee

FL

32301

City

State

Zip

Email winnsr@earthlink.net

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against (The Chair will read this information into the record.)

Representing Florida Osteopathic Medical Association

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

**THE FLORIDA SENATE**  
**APPEARANCE RECORD**

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/6/18  
Meeting Date

SB 504  
Bill Number (if applicable)

Topic Influenza Virus & Streptococcal

Amendment Barcode (if applicable)

Name Dr. Suzy Wise

Job Title Pharmacist

Address 992 Shetland Ave  
Street

Phone 407 234 1829

Winter Springs FL 32708  
City State Zip

Email SuzyWiseRx@gmail.com

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing \_\_\_\_\_

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

**This form is part of the public record for this meeting.**



THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/6/18

Meeting Date

SB 524

Bill Number (if applicable)

Topic Influenza Virus

Amendment Barcode (if applicable)

Name Aimee Diaz Lyon

Job Title

Address 119 South Monroe Street #200

Phone 850-205-9000

Street

Tallahassee FL 32301

Email aimee.diazlyon@mhbfirm.com

City

State

Zip

Speaking: For [ ] Against [X] Information [ ]

Waive Speaking: In Support [ ] Against [X] (The Chair will read this information into the record.)

Representing Florida Academy of Family Physicians

Appearing at request of Chair: Yes [ ] No [X]

Lobbyist registered with Legislature: Yes [X] No [ ]

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

**THE FLORIDA SENATE**  
**APPEARANCE RECORD**

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

524  
Bill Number (if applicable)

Meeting Date \_\_\_\_\_

Amendment Barcode (if applicable) \_\_\_\_\_

Topic Flu tests

Name Melissa Ramba

Job Title Vice President

Address 227 S Adams St.

Phone 850-570-0269

Street  
Tallahassee FL

Email Melissa@PRF.org

City State Zip

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing Florida Retail Federation

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

*While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.*

**This form is part of the public record for this meeting.**

THE FLORIDA SENATE  
**APPEARANCE RECORD**

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/6/2018

Meeting Date

SB524

Bill Number (if applicable)

Topic pharmacists treating flu

Amendment Barcode (if applicable)

Name MIA DIAZ

Job Title Exec. Assistant & Office Manager

Address 4537 Louvinia Ct.

Phone \_\_\_\_\_

Street

Tallahassee

Florida

32311

Email MDIAZ@FLORIDATAX

City

State

Zip

watch.org

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing Florida Tax Watch

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

**THE FLORIDA SENATE**  
**APPEARANCE RECORD**

Feb. 6, 18  
Meeting Date

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

524  
Bill Number (if applicable)

Topic \_\_\_\_\_

Amendment Barcode (if applicable)

Name Toni Large

Job Title \_\_\_\_\_

Address 519 E. Park Ave

Phone (850) 556-1461

Tallahassee, FL 32308

Email toni@sulawid

Street  
City State Zip

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing Florida College of Emergency Physicians

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

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**THE FLORIDA SENATE**  
**APPEARANCE RECORD**

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/16/18  
Meeting Date

524  
Bill Number (if applicable)

Topic Test and Treat

Amendment Barcode (if applicable)

Name Kathly Baldwin

Job Title Florida Society Health System Pharmacist

Address 647 Barton Village Dr.

Phone 904-753-335  
*Immediate Past Pres*

Jal, FL 32258  
City State Zip

Email Kathly Baldwin@bracy.com

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing FSMP

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

# APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/6/18

Meeting Date

SB 524

Bill Number (if applicable)

Topic Influenza Virus

Amendment Barcode (if applicable)

Name Dr. Christie Alexander

Job Title \_\_\_\_\_

Address 13241 Bartram Park Blvd. #1321  
Street

Phone ~~850~~ 904-726-0949

Jacksonville FL 32258  
City State Zip

Email christie.alexander@med.fsu.edu

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing Florida Academy of Family Physicians

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

**THE FLORIDA SENATE**  
**APPEARANCE RECORD**

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/6/2018

Meeting Date

5  
824

Bill Number (if applicable)

Topic Flu/Strep testing

Amendment Barcode (if applicable)

Name Sally West

Job Title Regional Director, Walgreens

Address 3810 Buck Lake Rd #C321

Phone 224-723-2650

Street

Tallahassee, FL 32317

Email sally.west@walgreens.com

City

State

Zip

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing Walgreens

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

**The Florida Senate**  
**BILL ANALYSIS AND FISCAL IMPACT STATEMENT**

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

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Prepared By: The Professional Staff of the Committee on Health Policy

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**BILL:** CS/SB 758

**INTRODUCER:** Health Policy Committee and Senators Gibson and Torres

**SUBJECT:** Diabetes Educators

**DATE:** February 6, 2018      **REVISED:** \_\_\_\_\_

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto-Van Winkle	Stovall	HP	<b>Fav/CS</b>
2.	_____	_____	AHS	_____
3.	_____	_____	AP	_____

**Please see Section IX. for Additional Information:**  
COMMITTEE SUBSTITUTE - Substantial Changes

**I. Summary:**

CS/SB 758 creates a new health care profession, the diabetes educator. The bill defines a diabetes educator as a health care practitioner registered under this new law who has demonstrated a comprehensive knowledge of and experience in prediabetes, diabetes prevention, diabetes education and who provides diabetes self-management training (DSMT), as defined in the bill. However, a licensed health care practitioner may practice within the scope of his or her license without this voluntary registration. The bill prohibits any person from representing himself or herself as a diabetes educator without first registering with the Department of Health (DOH). The bill provides requirements for registration and authorizes the DOH to develop rules for renewal procedures, fees, and disciplinary action.

The DOH must implement the registration and regulation of the diabetes educator by July 1, 2019.

The effective date of the bill is July 1, 2018.



## II. Present Situation:

Diabetes is a group of diseases in which the body produces too little insulin,<sup>1</sup> is unable to use insulin efficiently, or both. When diabetes is not controlled, glucose and fats remain in the blood and eventually cause damage to vital organs.

The most common forms of diabetes are:

- **Type 1:** Sometimes known as juvenile diabetes, Type 1 is usually first diagnosed in children and adolescents and accounts for about 5 percent of all diagnosed cases. Type 1 diabetes is an autoimmune disease in which the body's own immune system destroys cells in the pancreas that produce insulin. Type 1 may be caused by genetics, the environment, or other risk factors. At this time, there is no method to prevent or cure Type 1 diabetes, and treatment requires the lifetime use of insulin by injection or pump.
- **Type 2:** Sometimes known as "adult-onset diabetes," Type 2 accounts for about 95 percent of all diagnosed diabetes in adults; and is usually associated with older age, obesity, lack of physical activity, family history, or a personal history of gestational diabetes. Studies have shown that healthy eating, regular physical activity, and weight loss can prevent or delay the onset of Type 2 diabetes or eliminate the symptoms and effects post-onset.
- **Gestational diabetes:** This type of diabetes develops and is diagnosed as a result of pregnancy in two to ten percent of pregnant women. Gestational diabetes can cause health problems during pregnancy for both the mother and child. Children whose mothers have gestational diabetes are at an increased risk of developing obesity and Type 2 diabetes.<sup>2</sup>

Complications of diabetes include:

- Heart disease;
- Stroke;
- High blood pressure (hypertension);
- Blindness and other eye problems;
- Kidney disease;
- Nervous system disorders;
- Vascular disease; and
- Amputations.<sup>3</sup>

Death rates for heart disease and the risk of stroke are about two to four times higher among adults with diabetes than among those without diabetes. Diabetes and its potential health consequences can be managed through physical activity, diet, self-management training, and, when necessary, medication.<sup>4</sup>

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<sup>1</sup> Insulin is a hormone that allows glucose (sugar) to enter cells and be converted to energy. Merriam-Webster, available at <http://www.merriam-webster.com/dictionary/insulin> (last visited Jan. 31, 2018).

<sup>2</sup> U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, *Diabetes Report Card*, (2014), p. 4, available at <http://www.cdc.gov/diabetes/pdfs/library/diabetesreportcard2014.pdf>, (last visited Jan. 31, 2018); See also U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, *About Diabetes*, available at <https://www.cdc.gov/diabetes/basics/diabetes.html> (last visited Jan. 31, 2018).

<sup>3</sup> U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, *Diabetes Complications*, available at <https://www.cdc.gov/diabetestv/diabetes-complications.html> (last visited Jan. 31, 2018).

<sup>4</sup> *Id.*

People with “pre-diabetes” are at high risk of developing Type 2 diabetes, heart disease, and stroke. Their blood glucose levels are higher than normal, but not high enough to be classified as diabetes.<sup>5</sup> Although an estimated 33 percent of adults in the United States have pre-diabetes, less than ten percent of them report having been told they have the condition. Thus, awareness of the risk is low. People with pre-diabetes who lose five to seven percent of their body weight and get at least 150 minutes per week of moderate physical activity can reduce the risk of developing Type 2 diabetes by 58 percent.<sup>6</sup>

Risk factors for diabetes include:<sup>7</sup>

- Being over the age of 45;
- Overweight;
- Having a parent or sibling with diabetes;
- Having a minority family background;
- Developing diabetes while pregnant, gave birth to a baby weighing nine pounds or more; and
- Being physically active less than three times per week.

Persons with any of the above risk factors are five to 15 times more likely to develop Type 2 diabetes.<sup>8</sup> The Centers for Disease Control and Prevention (CDC) estimates that as many as one out of every three American adults has pre-diabetes, and half of all Americans aged 65 years and older have pre-diabetes.<sup>9</sup>

In 2013, the American Diabetes Association (ADA)<sup>10</sup> released a report updating its earlier studies estimating the fiscal impact of diagnosed diabetes. In 2012, the total estimated cost of diagnosed diabetes in the United States was \$245 billion, including \$176 billion in direct medical costs and \$69 billion in reduced productivity. This represents a 41 percent increase over the 2007 estimate. The largest components of these costs were hospital inpatient care (43 percent) and medications to treat complications (18 percent). People with diagnosed diabetes incur average medical costs of about \$13,700 per year, of which about \$7,900 is attributed to diabetes. Care for people with diagnosed diabetes accounts for more than one in five dollars spent on health care in the United States, and more than half of that is directly attributable to diabetes. Overall, average medical expenses for a person with diabetes are 2.3 times higher than they are for a person without diabetes.<sup>11</sup>

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<sup>5</sup> See Mayo Clinic, Patient Care and Health information, Diseases and Conditions, *Prediabetes*, <https://www.mayoclinic.org/diseases-conditions/prediabetes/symptoms-causes/syc-20355278>, (last visited Jan. 31, 2018)

<sup>6</sup> *Supra* note 2.

<sup>7</sup> *Id.*

<sup>8</sup> Florida Department of Health, *Prediabetes, What is Prediabetes?*, <http://www.floridahealth.gov/diseases-and-conditions/diabetes/prediabetes.html> (last visited Jan. 31, 2018).

<sup>9</sup> *Id.*

<sup>10</sup> The ADA was founded in 1940 by 26 physicians. It remained an organization for health care professionals during its first 30 years. In 1970, the Association welcomed general members. In the years since, it has grown to include a network of more than 1 million volunteers. See American Diabetes Association, *75 Years of Progress*, <http://www.diabetes.org/about-us/75th-anniversary/> (last visited Jan. 31, 2018).

<sup>11</sup> American Diabetes Association, *Economic Costs of Diabetes in the U.S. in 2012*, *Diabetes Care* 36: 1033 – 1046, 2013, available at, <http://care.diabetesjournals.org/content/36/4/1033.full.pdf+html> (last visited Jan. 31, 2018).

## Diabetes in Florida

In Florida, it is estimated that over 2.4 million people have diabetes and over 5.8 million have pre-diabetes.<sup>12</sup> Over the past 20 years, the prevalence of diagnosed diabetes among Florida adults more than doubled, increasing from 5.2 percent in 1995 to 11.2 percent in 2014.<sup>13</sup> The CDC projects that one out of three adults could have diabetes by 2050 if trends continue, due to an aging population more likely to develop Type 2 diabetes, increases in minority groups that are at high risk for Type 2 diabetes, and people with diabetes living longer.<sup>14</sup> This is of particular concern in Florida which has the largest population of adults ages 65 and older in the nation.<sup>15</sup>

In 2014, approximately one out of 10 mothers giving birth in Florida experienced gestational diabetes during their pregnancy. Gestational diabetes puts mothers at an increased risk of developing Type 2 diabetes later in life, increases the risk of birth complications, and increases the risk of the infant being obese and developing Type 2 diabetes in the future. While the data for diabetes in youth are somewhat limited, studies have shown that the number of youth being diagnosed with Type 2 diabetes is increasing. More than 18,000 new cases of Type 1 diabetes and more than 5,000 new cases of Type 2 diabetes are estimated to be diagnosed among US youth younger than age 20 each year.<sup>16</sup>

Diabetes was the seventh leading cause of death in 2014 in Florida.<sup>17</sup> The prior year, diabetes had been the sixth leading cause of death. As a percentage of total deaths in the state, diabetes accounted for 2.9 percent of all deaths, and over a three year period (2012 - 2014), diabetes had an age adjusted death rate per 100,000 of 19.7 or 15,597 deaths.<sup>18</sup>

## Florida's Diabetes Advisory Council

The Diabetes Advisory Council (DAC) was created by the Florida Legislature over 40 years ago, as mandated by s. 385.203, F.S., to “guide a statewide comprehensive approach to diabetes prevention, diagnosis, education, care, treatment, impact, and costs thereof.” Members, are appointed by the Governor to represent professional sectors involved in diabetes prevention and care, as well as citizens with diabetes and other citizen advocates. In 2015, the Florida Legislature added a requirement to the DAC to prepare a report describing the public health

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<sup>12</sup> American Diabetes Association, (2015, December). Fast Facts - *Data and Statistics-About Diabetes*, available at [http://professional.diabetes.org/content/fast-facts-data-and-statistics-about-diabetes/?loc=dorg\\_statistics](http://professional.diabetes.org/content/fast-facts-data-and-statistics-about-diabetes/?loc=dorg_statistics) (last visited Jan. 31, 2018).

<sup>13</sup> Florida Department of Health, Florida Diabetes Advisory Council, *2017 Florida Diabetes Report*, p.7., available at: <http://www.floridahealth.gov/provider-and-partner-resources/dac/documents/dac-report-january2017.pdf> (last visited Jan. 31, 2018).

<sup>14</sup> U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, *Number of Americans with Diabetes Projected to Double or Triple by 2050*, available at <https://www.cdc.gov/media/pressrel/2010/r101022.html> (last visited Jan. 31, 2018).

<sup>15</sup> *Supra* note 13.

<sup>16</sup> U.S. Department of Health and Human Services, Centers for Disease Control and Prevention *Diabetes Report Card 2014*, available at <http://www.cdc.gov/diabetes/pdfs/library/diabetesreportcard2014.pdf> (Last visited Jan. 31, 2018).

<sup>17</sup> Florida Department of Health, *Florida Vital Statistics Annual Report 2017*, p. 18, <http://www.flpublichealth.com/VSBOOK/pdf/2014/Deaths.pdf>, (last visited Jan. 31, 2018).

<sup>18</sup> Florida Department of Health, *Florida Charts: Diabetes Deaths - Three Year Trends*, <http://www.floridacharts.com/charts/DataViewer/DeathViewer/DeathViewer.aspx?indNumber=0090> (last visited Jan. 31, 2018).

consequences and financial impact on the state of all Types of diabetes and its complications. The legislation instructed the DAC to collaborate with the DOH, Department of Management Services – Division of State Group Insurance (DSGI), and the Agency for Health Care Administration to collect data about diabetes and state programs that address diabetes, as well as develop an action plan to reduce the impact of diabetes.<sup>19</sup> Recommendation number five includes recognizing and reimbursing diabetes educators for providing diabetes self-management education.<sup>20</sup>

### **ADA Standards of Medical Care in Diabetes**

The ADA’s “Standards of Medical Care in Diabetes,” referred to as the “Standards of Care,” are intended to provide clinicians, patients, researchers, payers, and other interested individuals with the components of the following:

- Diabetes care;
- General treatment goals; and
- Tools to evaluate the quality of care.<sup>21</sup>

The Standards of Care recommendations are not intended to preclude clinical judgment and must be applied in the context of excellent clinical care, with adjustments for individual preferences, comorbidities, and other patient factors. The recommendations include screening, diagnostic, and therapeutic actions that are known or believed to favorably affect health outcomes of patients with diabetes.<sup>22</sup>

### **Diabetes Educators**

The ADA defines a “diabetes educator” as, “a health care professional who teaches people who have diabetes how to manage their diabetes.”<sup>23</sup> Diabetes educators are found in hospitals, physician offices, managed care organizations, home health care, and other settings.<sup>24</sup>

The State of Florida does not currently license or regulate diabetes educators. The existing scope of practice in Florida for the following health care professions includes patient or client education, and that education can relate to diabetes:

- Allopathic Physician;
- Osteopathic Physician;
- Podiatric Physician;
- Chiropractic Physician;
- Dentist;
- Pharmacist;
- Advanced Registered Nurse Practitioner (ARNP, CNS, CRNA);
- Physician Assistant;

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<sup>19</sup> *Supra* note 13.

<sup>20</sup> *Id.* at pp. 64 - 65.

<sup>21</sup> American Diabetes Association, Diabetes Care 2018 Jan; 41(Supplement 1): S1-S2, *Introduction - Standards of Care in Diabetics – 2018*, [http://care.diabetesjournals.org/content/41/Supplement\\_1/S1](http://care.diabetesjournals.org/content/41/Supplement_1/S1) (last visited Jan. 31, 2018).

<sup>22</sup> *Id.*

<sup>23</sup> *Id.*

<sup>24</sup> *Id.*

- Registered Nurse;
- Dental Hygienist;
- Licensed Practical Nurse;
- Paramedic;
- Emergency Medical Technician;
- Dietitian/Nutritionist;
- Orthotist;
- Acupuncturist;
- Athletic Trainer;
- Physical Therapist;
- Massage Therapist;
- Prosthetist;
- Midwifery;
- Optician;
- Optometrist;
- School Psychologist;
- Orthotic Fitter;
- Mental Health Counselor;
- Clinical Psychologist; and
- Clinical Social Worker.<sup>25</sup>

Kentucky enacted a diabetes educator law in 2013, and Indiana did so in 2016.<sup>26</sup> Both are under the respective state's BOM. Kentucky provides three paths for individuals to become licensed as diabetes educators. An individual must file an application, pay a fee, and demonstrate completion of any one of the following:

- A board-approved course in diabetes education with demonstrable experience in the care of people with diabetes under supervision that meets requirements specified in administrative regulations promulgated by the board;<sup>27</sup> or
- The credentialing program of the American Association of Diabetes Educators (AADE) or the National Certification Board for Diabetes Educators (NCBDE); or
- An equivalent credentialing program as determined by the board.

Indiana's law is similar to Kentucky's as a diabetes educator license can be obtained by demonstrating completion of one of the four following:

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<sup>25</sup> See chs. 457, 458, 459, 460, 461, 462, 463, 464, 465, 466, 467, 478, 480, 484, 486, 490; and 491, F.S.; and part I, part II, part III, part V, part X, part XIII, and part XIV of ch. 468, F.S.; and part III or part IV of ch. 483, F.S.

<sup>26</sup> See American Association of Diabetes Educators, *State Legislation* <https://www.diabeteseducator.org/advocacy/state-legislation> (last visited Jan. 31, 2018).

<sup>27</sup> 201 KAR 45:110 (2015), requires the apprentice diabetes educator to accumulate at least 750 hours of supervised work experience in five years with 250 of the hours being obtained in the 12 months preceding licensure application. The apprentice is required to interact with the supervisor at least two hours quarterly, one hour of which must be in person. A supervisor shall not supervise more than four apprentices at a time. The supervision process shall focus on: (a) Identifying strengths, developmental needs, and providing direct feedback to foster the professional development of the apprentice diabetes educator; (b) Identifying and providing resources to facilitate learning and professional growth; (c) Developing awareness of professional and ethical responsibilities in the practice of diabetes education; and (d) Ensuring the safe and effective delivery of diabetes education services and fostering the professional competence and development of the apprentice diabetes educator.

- The AADE core concepts course<sup>28</sup> with demonstrable experience in the care of individuals with diabetes under supervision that meets requirements specified in rules adopted by the board.
- The credentialing program of the AADE;
- The credentialing program of the NCBDE; or
- An equivalent credentialing program as determined by the board.

The AADE was founded in 1973, as a multi-disciplinary professional membership organization dedicated to improving diabetes care through education. It has more than 14,000 members including nurses, dietitians, pharmacists and others. The AADE offers the Board Certified-Advanced Diabetes Management (BC-ADM) credential.<sup>29</sup>

Healthcare professionals who hold BC-ADM certification, if within their scope of practice, are trained to:

- Adjust medications;
- Treat and monitor complications and other comorbidities;
- Counsel patients on lifestyle modifications;
- Address psychosocial issues; and
- Participate in research and mentoring.

Certification as a BC-ADM requires a current active licensure/registration as a registered nurse, dietitian, pharmacist, physician or physician assistant, a master's or higher level degree, and 500 clinical practice hours within 48 months prior to taking the certification exam.<sup>30</sup>

The NCBDE was established in 1986 as an independent organization that promotes the interests of diabetes educators and the public by granting certification to qualified health professionals. The NCBDE offers the Certified Diabetes Educator (CDE) credential. Individuals holding the CDE credential educate people affected by diabetes to manage the condition and promote self-management in order to optimize health outcomes.<sup>31</sup>

Certification as a CDE requires active licensure/registration as a psychologist, registered nurse, occupational therapist, optometrist, pharmacist, physical therapist, physician, podiatrist, dietitian with a Commission on Dietetic Registration (CDR), or a health professional with a master's degree or higher in social work. Professional practice experience, continuing education and an examination are also required.<sup>32</sup>

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<sup>28</sup> American Association of Diabetes Educators, *CORE Concepts Course On Line*, is available for a cost of between \$386 - \$586, available at <https://www.diabeteseducator.org/education-career/online-courses/ccc-online>, (last visited Jan. 31, 2018).

<sup>29</sup> The American Association of Diabetes Educators, *About AADE*, <https://www.diabeteseducator.org/about-aade> (last visited Jan. 31, 2018).

<sup>30</sup> *Id.*

<sup>31</sup> National Certification Board for Diabetes Educators, *History*, <http://www.ncbde.org/about/history/> (last visited Jan. 31, 2018).

<sup>32</sup> *Id.*

The CDC has also established the CDC National Diabetes Recognition Program (NDRP) as part of the National Diabetes Prevention Program (NDPP).<sup>33</sup> The NDPP is a partnership of public and private organizations working to reduce the growing problem of lack of public education on prediabetes and Type 2 diabetes.<sup>34</sup> A key part of the NDPP is the lifestyle change program to prevent or delay Type 2 diabetes. Hundreds of in-person, and online, lifestyle change programs nationwide teach participants to make CDC approved lasting lifestyle changes, like eating healthier, adding physical activity into a daily routine, and improving coping skills. To ensure high quality, the CDC recognizes lifestyle change programs that meet certain standards and show they can achieve results. These standards include following an approved curriculum, facilitation by a trained lifestyle coach, and submitting data each year to show that the program is having an impact. The NDPP must use a lifestyle coach to deliver the program to participants. Many lifestyle coaches are registered dietitians or registered nurses, but no credentials are required;<sup>35</sup> and the CDC has a free lifestyle coach facilitator training guide available on its website.<sup>36</sup>

The AADE also offers NDPP diabetes lifestyle coach training based on the curriculum of the CDC in a two-day, in person, course for \$750 - \$850 to acquire all necessary skills to deliver a successful CDC NDRP/NDPP Program.<sup>37</sup>

### **The Sunrise Act and Sunrise Questionnaire**

The Sunrise Act (the act), codified in s. 11.62, F.S., requires the Legislature to consider specific factors in determining whether to regulate a new profession or occupation. The legislative intent in the act provides that:

- No profession or occupation be subject to regulation unless the regulation is necessary to protect the public health, safety, or welfare from significant and discernible harm or damage and that the state's police power be exercised only to the extent necessary for that purpose; and
- No profession or occupation be regulated in a manner that unnecessarily restricts entry into the practice of the profession or occupation or adversely affects the availability of the services to the public.

The Legislature must review all legislation proposing regulation of a previously unregulated profession or occupation and make a determination for regulation based on consideration of the following:

- Whether the unregulated practice of the profession or occupation will substantially harm or endanger the public health, safety, or welfare, and whether the potential for harm is recognizable and not remote;

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<sup>33</sup> U.S. Department of Health and Human Services, Center for Disease Control and Prevention, *Diabetes Prevention Recognition Program, Standards and Operating Procedures* (January 1, 2015), <http://www.cdc.gov/diabetes/prevention/pdf/dprp-standards.pdf> (last visited Jan. 31, 2018).

<sup>34</sup> U.S. Department of Health and Human Services, Center for Disease Control and Prevention, *What Is the National DPP?* available at <http://www.cdc.gov/diabetes/prevention/about/index.html> (last visited Jan. 31, 2018).

<sup>35</sup> *Supra* note 32, at 25.

<sup>36</sup> U.S. Department of Health and Human Services, Center for Disease Control and Prevention, *National Diabetes Prevention Program, Life Coach Facilitation Guide*, [http://www.cdc.gov/diabetes/prevention/pdf/curriculum\\_intro.pdf](http://www.cdc.gov/diabetes/prevention/pdf/curriculum_intro.pdf) (last visited Jan. 31, 2018).

<sup>37</sup> American Association of Diabetes Educators, *AADE Diabetes Prevention Program Lifestyle Coach Training*, <https://www.diabeteseducator.org/practice/diabetes-prevention-program/lifestyle-coach-training> (last visited Jan. 31, 2018).

- Whether the practice of the profession or occupation requires specialized skill or training, and whether that skill or training is readily measurable or quantifiable so that examination or training requirements would reasonably assure initial and continuing professional or occupational ability;
- Whether the regulation will have an unreasonable effect on job creation or job retention in the state or will place unreasonable restrictions on the ability of individuals who seek to practice or who are practicing a given profession or occupation to find employment;
- Whether the public is or can be effectively protected by other means; and
- Whether the overall cost-effectiveness and economic impact of the proposed regulation, including the indirect costs to consumers, will be favorable.

The act requires the proponents of legislation for the regulation of a profession or occupation to provide specific information in writing to the state agency that is proposed to have jurisdiction over the regulation and to the legislative committees of reference.<sup>38</sup> This required information is traditionally compiled in a “Sunrise Questionnaire.”

The Florida Senate Sunrise Questionnaire to aid the Legislature in determining the need to regulate diabetes educators has been provided to the Senate Health Policy Committee. The Senate Sunrise Questionnaire was received March 30, 2017,<sup>39</sup> for similar proposed legislation in 2017.<sup>40</sup>

The Senate Sunrise Questionnaire indicates that the AADE is seeking regulation in Florida; and that in 2017 there were approximately 700 individuals who were members of the AADE in Florida, many having earned the CDE certification from the NCBDE or the BC-ADM.

The Questionnaire notes that practitioners typically deal with individuals with or at risk of diabetes and related conditions to achieve behavioral change which will lead to better clinical outcomes and improved health status. The questionnaire notes that a physician typically refers a patient to a nurse who practices in diabetes education, nutritionist, dietician or podiatrist for diabetic education. Registration would bring attention to the benefits of DSMT programs. The questionnaire further notes that marketplace factors will not be as effective as government regulation because places like grocery stores, drug stores, massage establishments, and spas offer diabetes education or wellness programs, and these programs are not recognized by the American Diabetes Association. The legislation would permit health care practitioners to become recognized as Florida Registered Diabetes Educators.

The restrictions on the practice of providing diabetes education may affect the public’s access to these services.

### **III. Effect of Proposed Changes:**

CS/SB 758 creates part XVII of ch. 468, F.S., entitled “Diabetes Educators,” to establish a regulated profession in Florida. Registration is voluntary unless a person holds himself or herself

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<sup>38</sup> See s. 11.62(4)(a)-(m), F.S.

<sup>39</sup> See Florida Senate Sunrise Questionnaire, Diabetes Educators, (March 30, 2017) (on file with the Senate Committee on Health Policy).

<sup>40</sup> See SB 1578 (2017 Regular Session).



out as a diabetes educator or provides DSMT, as defined in the bill. However, a licensed health practitioner may provide services within the scope of his or her license.

The bill makes legislative findings that the provision of DSMT by unregistered and incompetent practitioners presents a danger to the public health and safety; and that it is the intent of the Legislature to prohibit persons who fall below the minimum competency standards for a diabetes educator from providing DSMT in Florida.

The bill defines the following terms for the profession of diabetes educator:

- “Diabetes educator” as a healthcare practitioner registered under part XVII, of ch. 468, F.S., who has demonstrated a comprehensive knowledge of and experience in prediabetes, diabetes prevention, and diabetes education; and who provides DSMT; and
- “Diabetes self-management education and training” is the assessment and development of a plan of care for a person with diabetes through a collaborative process through which the person gains the knowledge and skills necessary to modify behavior and successfully self-manage the disease as provided for in the national standards published by the American Diabetes Association.

The bill requires that the DOH issue a registration to an applicant who submits the following to the DOH:

- Documentation of:
  - Certification as a Certified Diabetes Educator (CDE) by the National Certification Board for Diabetes Educators (NCBDE); or
  - Certification in Board Certified-Advanced Diabetes Management (BC-ADM) by the American Association of Diabetes Educators (AADF); or
  - Completion of 250 practice hours of diabetes education, of which at least 100 hours must be earned in the calendar year preceding application; a passing score on the NCBDE registration examination; and licensure as a health care practitioner as defined in s. 456.001, F.S.

The bill requires the DOH to renew a registration upon receipt of a renewal application and a biennial renewal fee. The DOH is also required to adopt rules establishing procedures for biennial registration renewal.

The bill creates s. 468.934, F.S., to require the DOH to establish, by rule, the following fees:

- A nonrefundable application fee, not to exceed \$100.00;
- An initial registration fee, not to exceed \$100.00;
- A biennial renewal fee, not to exceed \$80.00; and
- A fee for reactivation of an inactive registration, not to exceed \$135.00.

The fees must be adequate to support the registration program.

The bill creates s. 468.935, F.S., which specifies prohibited acts and creates exemptions. A person may not provide DSMT, or represent himself or herself as a diabetes educator unless he or she is registered with the DOH under this part. This part does not prohibit or restrict a health care practitioner as defined in ch. 456, F.S., from practicing within the scope of his or her

profession. However, a licensed health care practitioner desiring to use the credential of diabetes educator must obtain additional training in diabetes education as noted above, pass the NCBDE examination, and register with the DOH.

A person employed by the federal government performing official duties is also exempt from registration.

The DOH is required to implement the provisions of the bill by July 1, 2019.

The bill has an effective date of July 1, 2018.

#### **IV. Constitutional Issues:**

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

#### **V. Fiscal Impact Statement:**

A. Tax/Fee Issues:

The bill requires the DOH to establish fees as follows:

- A nonrefundable application fee, not to exceed \$100.00;
- An initial registration fee, not to exceed \$100.00;
- A biennial renewal fee, not to exceed \$80.00; and
- A fee for reactivation of an inactive registration, not to exceed \$135.00.

B. Private Sector Impact:

For a licensed healthcare practitioner, the registration is voluntary. For others, one must be registered and pay the applicable fees to use the title of diabetes educator or to engage in DSMT.

C. Government Sector Impact:

The DOH will experience an increase in revenues associated with diabetes educator application and initial and renewal fees; but will incur an increase in workload and costs associated with the registration and regulation of diabetes educators. The fees must be adequate to implement and administer this part.

**VI. Technical Deficiencies:**

The bill does not amend s. 20.43(3)(g), F.S., to include the newly created profession of diabetes educators in the listing of professions under the responsibility of the Division of Medical Quality Assurance.

**VII. Related Issues:**

The effective date of the act is July 1, 2018, and providing an effective date prior to the requirement for the DOH to implement registration and regulation may facilitate implementation of the act. However, the prohibited act takes effect ostensibly a year before the registration is available. Section 468.935(1), F.S., could be amended to be effective July 1, 2019.

The bill authorizes an independent practice without any medical oversight. The Dietetics and Nutrition Practice Council is under the BOM and those practitioners operate pursuant to physician's orders and oversight. Similarly, the diabetes educator functions are similar to those of nurses who operate pursuant to physician or other advanced practitioner orders and oversight.

The bill does not distinguish the standards of practice of the diabetes educators from dietitians, nutritionists, or nurses who also follow ADA Standards.

**VIII. Statutes Affected:**

This bill substantially amends section 456.001 of the Florida Statutes.

This bill creates the following sections of the Florida Statutes: 468.931, 468.932, 468.933, 468.934, and 468.935.

**IX. Additional Information:**

- A. **Committee Substitute – Statement of Substantial Changes:**  
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

**CS by Health Policy on February 6, 2018:**

Deletes certification as a clinical exercise physiologist, registered clinical exercise physiologist, or having a master's degree or higher in social work, in conjunction with 250 hours in diabetes education and passage of the NCBDE examination, as a pathway for registration as a diabetes educator.

- B. **Amendments:**

None.



920380

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
02/06/2018	.	
	.	
	.	
	.	

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The Committee on Health Policy (Gibson) recommended the following:

**Senate Amendment**

Delete lines 79 - 86  
and insert:  
proof of licensure as a health care practitioner as defined in  
s. 456.001.

By Senator Gibson

6-00529A-18

2018758\_\_

1                                   A bill to be entitled  
2       An act relating to diabetes educators; amending s.  
3       456.001, F.S.; redefining the term "health care  
4       practitioner" to include diabetes educators; creating  
5       part XVII of ch. 468, F.S., entitled "Diabetes  
6       Educators"; providing legislative findings and intent;  
7       requiring implementation by a specified date; defining  
8       terms; providing requirements for registration as a  
9       diabetes educator; requiring the Department of Health  
10      to renew a registration under certain circumstances;  
11      requiring the department to adopt rules for biennial  
12      renewal of registrations; requiring the department to  
13      establish specified fees; prohibiting an unregistered  
14      person from certain activities relating to diabetes  
15      self-management training; providing exemptions;  
16      authorizing the department to take disciplinary action  
17      against an applicant or registrant for specified  
18      violations; authorizing rulemaking; providing an  
19      effective date.

20  
21 Be It Enacted by the Legislature of the State of Florida:

22  
23       Section 1. Subsection (4) of section 456.001, Florida  
24       Statutes, is amended to read:

25       456.001 Definitions.—As used in this chapter, the term:

26       (4) "Health care practitioner" means any person licensed or  
27       registered under chapter 457; chapter 458; chapter 459; chapter  
28       460; chapter 461; chapter 462; chapter 463; chapter 464; chapter  
29       465; chapter 466; chapter 467; part I, part II, part III, part

6-00529A-18

2018758\_\_

30 V, part X, part XIII, ~~or~~ part XIV, or part XVII of chapter 468;  
31 chapter 478; chapter 480; part III or part IV of chapter 483;  
32 chapter 484; chapter 486; chapter 490; or chapter 491.

33 Section 2. Part XVII of chapter 468, Florida Statutes,  
34 consisting of sections 468.931 through 468.935, Florida  
35 Statutes, is created to read:

36 PART XVII

37 DIABETES EDUCATORS

38 468.931 Legislative findings and intent; implementation.-

39 (1) The Legislature finds that the provision of diabetes  
40 self-management training by unregistered and incompetent  
41 practitioners presents a danger to the public health and safety.  
42 Therefore, it is the intent of the Legislature to prohibit  
43 diabetes educators who fall below minimum competency standards  
44 or who otherwise present a danger to the public health and  
45 safety from providing diabetes self-management training in this  
46 state.

47 (2) The Department of Health must implement the provisions  
48 of this part by July 1, 2019.

49 468.932 Definitions.-As used in this part, the term:

50 (1) "Department" means the Department of Health.

51 (2) "Diabetes educator" means a health care practitioner  
52 registered under this part who has demonstrated a comprehensive  
53 knowledge of and experience in prediabetes, diabetes prevention,  
54 and diabetes education and who provides diabetes self-management  
55 training.

56 (3) "Diabetes self-management training" means the  
57 assessment and development of a plan of care for a person with  
58 diabetes through a collaborative process through which the

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59 person gains the knowledge and skills necessary to modify  
60 behavior and successfully self-manage the disease as provided  
61 for in the national standards published by the American Diabetes  
62 Association.

63 468.933 Requirements for registration; registration  
64 renewal.—

65 (1) The department shall issue a registration to an  
66 applicant who has submitted to the department:

67 (a) A completed application in a form prescribed by the  
68 department.

69 (b) A registration fee, pursuant to s. 468.934.

70 (c)1. Proof of certification as a Certified Diabetes  
71 Educator by the National Certification Board for Diabetes  
72 Educators or certification in Board Certified—Advanced Diabetes  
73 Management by the American Association of Diabetes Educators; or

74 2. Proof of completion of at least 250 practice hours of  
75 diabetes education, of which at least 100 practice hours are  
76 earned in the calendar year immediately preceding application,  
77 and proof of passing the registration examination administered  
78 by the National Certification Board for Diabetes Educators; and  
79 at least one of the following:

80 a. Proof of licensure as a health care practitioner as  
81 defined in s. 456.001;

82 b. Proof of certification as a clinical exercise  
83 physiologist or Registered Clinical Exercise Physiologist by the  
84 American College of Sports Medicine; or

85 c. Proof of a master's degree or higher in social work from  
86 an accredited United States college or university.

87 (2) The department shall renew a registration under this

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88 section upon receipt of a renewal application and biennial  
89 renewal fee from a registrant. The department shall adopt rules  
90 establishing procedures for biennial renewal of registrations  
91 under this section.

92 468.934 Fees.—The department shall establish by rule the  
93 following fees to be paid by a person seeking registration or  
94 registration renewal as a diabetes educator. The fees must be  
95 adequate to implement and administer this part:

96 (1) A nonrefundable application fee, which may not exceed  
97 \$100.

98 (2) An initial registration fee, which may not exceed \$100.

99 (3) A biennial renewal fee, which may not exceed \$80.

100 (4) A fee for reactivation of an inactive registration,  
101 which may not exceed \$135.

102 468.935 Prohibited acts; exemptions.—

103 (1) A person may not provide diabetes self-management  
104 training, or represent himself or herself as being a diabetes  
105 educator, unless he or she is registered pursuant to this part.

106 (2) This section does not prohibit or restrict:

107 (a) An emergency medical technician or paramedic licensed  
108 under chapter 401 or a health care practitioner as defined in s.  
109 456.001 from engaging in, or practicing within, the scope of the  
110 occupation or profession for which he or she is licensed.

111 (b) A person employed by the Federal Government or any  
112 bureau, division, or agency of the Federal Government from  
113 discharging his or her official duties.

114 (3) The department may take disciplinary action pursuant to  
115 s. 456.072 against an applicant or registrant and may deny,  
116 revoke, or suspend registration or registration renewal for a



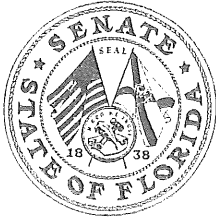
6-00529A-18

2018758\_\_

117 violation of this section.

118 (4) The department may adopt rules to implement and  
119 administer this section.

120 Section 3. This act shall take effect July 1, 2018.



# THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

**COMMITTEES:**  
Military and Veterans Affairs, Space, and  
Domestic Security, *Chair*  
Appropriations  
Appropriations Subcommittee on  
Transportation, Tourism, and Economic  
Development  
Commerce and Tourism  
Judiciary  
Regulated Industries

**JOINT COMMITTEE:**  
Joint Legislative Auditing Committee

**SENATOR AUDREY GIBSON**  
6th District

November 20, 2017

Senator Dana Young, Chair  
Committee on Health Policy  
530 Knott Building  
404 South Monroe Street  
Tallahassee, Florida 32399-1100

Chair Young:

I respectfully request that SB 758, relating to diabetes educators, be placed on the next committee agenda.

SB 758, provides requirements for registration as a diabetes educator and prohibits an unregistered person from certain activities relating to diabetes self-management training. The bill also requires the department to adopt rules for biennial registration renewal.

Thank you for your time and consideration.

Sincerely,

A handwritten signature in black ink that reads "Audrey Gibson".

Audrey Gibson  
State Senator  
District 6

101 E. Union Street, Suite 104, Jacksonville, Florida 32202 (904) 359-2553  
405 Senate Office Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5006

Senate's Website: [www.flsenate.gov](http://www.flsenate.gov)

**JOE NEGRON**  
President of the Senate

**ANITERE FLORES**  
President Pro Tempore

**THE FLORIDA SENATE**  
**APPEARANCE RECORD**

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/6/2018  
Meeting Date

758  
Bill Number (if applicable)

Topic Diabetes Educators

Amendment Barcode (if applicable)

Name Melanie Bostick

Job Title Vice President

Address 113 E. College Avenue

Phone (850) 688-3183

Tallahassee FL 32301  
City State Zip

Email melanie@libertypartnersfl.com

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing American Association of Diabetes Educators

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

**The Florida Senate**  
**BILL ANALYSIS AND FISCAL IMPACT STATEMENT**

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

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Prepared By: The Professional Staff of the Committee on Health Policy

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BILL: CS/SB 848

INTRODUCER: Health Policy Committee and Senator Grimsley

SUBJECT: Telepharmacy

DATE: February 6, 2018

REVISED: \_\_\_\_\_

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Looke</u>	<u>Stovall</u>	<u>HP</u>	<u>Fav/CS</u>
2.	_____	_____	<u>AP</u>	_____
3.	_____	_____	<u>RC</u>	_____

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**Please see Section IX. for Additional Information:**

COMMITTEE SUBSTITUTE - Substantial Changes

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**I. Summary:**

CS/SB 848 creates a new pharmacy permit for remote dispensing site pharmacies (RDSP). The bill defines “remote dispensing site pharmacy” and provides exceptions to current law for the operation of an RDSP. In an RDSP a registered pharmacy technician may dispense medicinal drugs under the supervision of an offsite pharmacist. The bill establishes requirements for RDSP permits including:

- Ownership and video surveillance for remote supervision by a Florida licensed pharmacist;
- A restriction that a remote dispensing site pharmacy must be located in a rural area and may not be located within 10 miles of a community pharmacy, with exceptions; and
- Policies and procedures that an RDSPs must maintain.

The bill allows an RDSP to store, hold, and dispense all medicinal drugs<sup>1</sup> including controlled substances listed in s. 893.03(3)-(5), F.S., but restricts an RDSP from storing, holding, and dispensing schedule II narcotic controlled substances. The bill restricts an RDSP from performing centralized prescription filling and a registered pharmacy technician working in an RDSP from performing sterile or complex nonsterile compounding.<sup>2</sup>

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<sup>1</sup> “Medicinal drugs” are defined in s. 465.003(8), F.S., as those substances or preparations commonly known as “prescription” or “legend” drugs which are required by federal or state law to be dispensed only on a prescription.

<sup>2</sup> Defined in s. 465.003(16), F.S., as the filling of a prescription by one pharmacy upon request by another pharmacy to fill or refill the prescription. The term includes the performance by one pharmacy for another pharmacy of other pharmacy duties such as drug utilization review, therapeutic drug utilization review, claims adjudication, and the obtaining of refill authorizations.

## II. Present Situation:

### Pharmacy Regulation

The Florida Pharmacy Act (act) regulates the practice of pharmacy in Florida and contains the minimum requirements for safe practice.<sup>3</sup> The Board of Pharmacy (board) is tasked with adopting rules to implement the provisions of the act and setting standards of practice within the state.<sup>4</sup> Any person who operates a pharmacy in Florida must have a permit, and as of July 1, 2017, there were 9,835 permitted pharmacies in the state.<sup>5</sup> The following permits are issued by the Department of Health (DOH):

- Community pharmacy – A permit is required for each location where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis.<sup>6</sup>
- Institutional pharmacy – A permit is required for every location in a hospital, clinic, nursing home, dispensary, sanitarium, extended care facility, or other facility where medicinal drugs are compounded, dispensed, stored, or sold.<sup>7</sup>
- Nuclear pharmacy – A permit is required for every location where radioactive drugs and chemicals within the classification of medicinal drugs are compounded, dispensed, stored, or sold. The term “nuclear pharmacy” does not include hospitals licensed under ch. 395, F.S., or the nuclear medicine facilities of such hospitals.<sup>8</sup>
- Special pharmacy – A permit is required for every location where medicinal drugs are compounded, dispensed, stored, or sold if the location does not otherwise meet an applicable pharmacy definition in s. 465.003, F.S.<sup>9</sup>
- Internet pharmacy – A permit is required for a location not otherwise licensed or issued a permit under this chapter, within or outside this state, which uses the Internet to communicate with or obtain information from consumers in this state to fill or refill prescriptions or to dispense, distribute, or otherwise practice pharmacy in this state.<sup>10</sup>
- Nonresident sterile compounding pharmacy – A permit is required for a registered nonresident pharmacy or an outsourcing facility to ship, mail, deliver, or dispense, in any manner, a compounded sterile product into this state.<sup>11</sup>
- Special sterile compounding – A separate permit is required for a pharmacy holding an active pharmacy permit that engages in sterile compounding.<sup>12</sup>

A pharmacy must pass an on-site inspection for a permit to be issued,<sup>13</sup> and the permit is valid only for the name and address to which it is issued.<sup>14</sup>

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<sup>3</sup> Chapter 465, F.S.

<sup>4</sup> Sections 465.005, 465.0155, and 465.022, F.S.

<sup>5</sup> Department of Health, *Senate Bill 848 Analysis* (Nov. 13, 2017) (on file with the Senate Committee on Health Policy).

<sup>6</sup> Sections 465.003(11)(a)1. and 465.018, F.S.

<sup>7</sup> Sections 465.003(11)(a)2. and 465.019, F.S.

<sup>8</sup> Sections 465.003(11)(a)3. and 465.0193, F.S.

<sup>9</sup> Sections 465.003(11)(a)4. and 465.0196, F.S.

<sup>10</sup> Sections 465.003(11)(a)5. and 465.0197, F.S.

<sup>11</sup> Section 465.0158, F.S.

<sup>12</sup> Rules 64B16-2.100 and 64B16-28.802, F.A.C. An outsourcing facility is considered a pharmacy and need to hold a special sterile compounding permit if it engages in sterile compounding.

<sup>13</sup> *Id.*

<sup>14</sup> Rule 64B16-28.100, F.A.C.

## Regulation of Pharmacists and Pharmacy Technicians

### Pharmacists

#### *Licensure Requirements*

A pharmacist is a person who is licensed under the act to practice the profession of pharmacy.<sup>15</sup> To be licensed as a pharmacist in Florida, a person must:<sup>16</sup>

- Be at least 18 years of age;
- Complete an application and remit an examination fee;
- Hold a degree from an accredited and approved school or college of pharmacy;<sup>17</sup>
- Have completed a board-approved internship; and
- Successfully complete the board-approved examination.

During each biennial licensure renewal cycle, a pharmacist must complete at least 30 hours of board-approved continuing education.<sup>18</sup> If a pharmacist is certified to administer vaccines or epinephrine, the pharmacist must complete a three-hour continuing education course on the safe and effective administration of vaccines and epinephrine autoinjections as a part of the biennial licensure renewal.<sup>19</sup>

#### *Scope of Practice*

The practice of the profession of pharmacy includes:<sup>20</sup>

- Compounding,<sup>21</sup> dispensing, and consulting concerning contents, therapeutic values, and uses of a medicinal drug;
- Consulting concerning therapeutic values and interactions of patent or proprietary preparations;
- Monitoring a patient's drug therapy and assisting the patient in the management of his or her drug therapy, including the review of the patient's drug therapy and communication with the patient's prescribing health care provider or other persons specifically authorized by the patient, regarding the drug therapy;
- Transmitting information from prescribers to their patients;

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<sup>15</sup> Section 465.003(10), F.S.

<sup>16</sup> Section 465.007, F.S. DOH may also issue a license by endorsement to a pharmacist who is licensed in another state upon meeting the applicable requirements set forth in law and rule. See s. 465.0075, F.S.

<sup>17</sup> If the applicant has graduated from a four-year undergraduate pharmacy program of a school or college of pharmacy located outside the United States, the applicant must demonstrate proficiency in English, pass the board-approved Foreign Pharmacy Graduate Equivalency Examination, and complete a minimum of 500 hours in a supervised work activity program within Florida under the supervision of a DOH-licensed pharmacist.

<sup>18</sup> Section 465.009, F.S.

<sup>19</sup> Section 465.009(6), F.S.

<sup>20</sup> Section 465.003(13), F.S.

<sup>21</sup> Rule 64B16-27.700, F.A.C., defines compounding as a professional act by a pharmacist incorporating ingredients to create a finished product for dispensing to a patient or to a practitioner for administration to a patient. The American Pharmacists Association, citing the U.S. Pharmacopeia Convention (USP) defines compounding as "the preparation, mixing, assembling, altering, packaging, and labeling of a drug, drug-delivery device, or device in accordance with a licensed practitioner's prescription, medication order, or initiative based on the practitioner/patient/ pharmacist/compounder relationship in the course of professional practice." See <http://www.pharmacist.com/frequently-asked-questions-about-pharmaceutical-compounding> (last visited Feb. 1, 2018).

- Administering vaccines to adults;<sup>22</sup>
- Administering epinephrine injections;<sup>23</sup> and
- Administering antipsychotic medications by injection.<sup>24</sup>

Pharmacists are specifically prohibited from altering a prescriber's directions, diagnosing or treating any disease, initiating any drug therapy, and practicing medicine or osteopathic medicine, unless permitted by law.<sup>25</sup>

Only a pharmacist or registered intern may:<sup>26</sup>

- Supervise or be responsible for the controlled substance inventory;
- Receive verbal prescriptions from a prescriber;
- Interpret and identify prescription contents;
- Engage in consultation with a health care practitioner regarding the interpretation of a prescription and date in a patient's profile record;
- Engage in professional communication with health care practitioners;
- Advise or consult with a patient, both as to the prescription and the patient profile record; and
- Perform certain duties related to the preparation of parenteral and bulk solutions.

Pharmacists must perform the final check of a completed prescription, thereby assuming complete responsibility for its preparation and accuracy.<sup>27</sup> A pharmacist must be personally available at the time of dispensing.<sup>28</sup> A prescription department is considered closed if a Florida-licensed pharmacist is not present and on duty unless the pharmacist leaves the prescription department to:<sup>29</sup>

- Consult, respond to inquiries, or provide assistance to customers or patients;
- Attend to personal hygiene needs; or
- Perform functions for which the pharmacist is responsible provided that such activities are performed in a manner that is consistent with the pharmacist's responsibility to provide pharmacy services.

### ***Prescription Department Managers***

Each community pharmacy must designate a licensed pharmacist as a prescription department manager.<sup>30</sup> The prescription department manager is responsible for maintaining all drug records, providing for the security of the prescription department, and ensuring that the all regulations of the practice of the profession of pharmacy are followed.<sup>31</sup> A pharmacist may only serve as the

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<sup>22</sup> See s. 465.189, F.S.

<sup>23</sup> Id.

<sup>24</sup> Section 465.1893, F.S.

<sup>25</sup> Supra note 21.

<sup>26</sup> Rule 64B16-27.1001(1)-(2), F.A.C. Section 465.003(12), F.S., defines a pharmacy intern as a person who is currently registered in, and attending, or is a graduate of a duly accredited college or school of pharmacy and is properly registered with DOH.

<sup>27</sup> Rule 64B16-27.1001(3), F.A.C.

<sup>28</sup> Rule 64B16-27.1001(4), F.A.C.

<sup>29</sup> Section 465.003(11)(b), F.S.

<sup>30</sup> Rules 64B16-27.104 and 64B16-27.450, F.A.C.

<sup>31</sup> Id.

prescription department manager of one pharmacy.<sup>32</sup> However, the board may grant an exception based on circumstances, such as the proximity of the pharmacies and the workload of the pharmacist.

## **Pharmacy Technicians**

### ***Registration Requirements***

Pharmacy technicians assist pharmacists in dispensing medications and are accountable to a supervising pharmacist who is legally responsible for the care and safety of the patients served.<sup>33</sup> A person must register with DOH to practice as a pharmacy technician. To register, an individual must:<sup>34</sup>

- Be at least 17 years of age;
- Submit an application and pay an application fee; and
- Complete a board-approved pharmacy technician training program.<sup>35</sup>

The pharmacy technician must renew the registration biennially. For each renewal cycle, a pharmacy technician must complete 20 continuing education hours, four of which must be live.<sup>36</sup>

### ***Pharmacy Technician Training Programs***

A pharmacy technician may only be registered with DOH if it completes a board-approved training program. These include pre-approved training programs that were accredited on or before April 1, 2017, by certain accreditation entities, such as the Accreditation Council on Pharmacy Education, as well as pharmacy technician training programs provided by a branch of the United States Armed Forces whose curriculum was developed on or before April 1, 2017.<sup>37</sup>

The board may review and approve other training programs that do not meet the criteria for pre-approval. Such programs must be licensed by the Commission for Independent Education or equivalent licensing authority or be within the public school system of this state, and offer a course of study that includes:<sup>38</sup>

- Introduction to pharmacy and health care systems;
- Confidentiality;
- Patient rights and the Health Insurance Portability and Accountability Act (HIPAA);
- Relevant federal and state law;
- Pharmaceutical topics, including medical terminology, abbreviations, and symbols; medication safety and error prevention; and prescriptions and medication orders;

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<sup>32</sup> Id.

<sup>33</sup> Pharmacy Technician Certification Board, Pharmacy Technicians, available at <https://www.ptcb.org/who-we-serve/pharmacy-technicians#.WnjALPwUIPZ> (last visited on Feb. 1, 2018).

<sup>34</sup> Section 465.014(2), F.S.

<sup>35</sup> An individual is exempt from the training program if he or she was registered as a pharmacy technician before January 1, 2011, and either worked as a pharmacy technician at least 1,500 hours under a licensed pharmacist or received certification from an accredited pharmacy technician program.

<sup>36</sup> Section 465.014(6), F.S.

<sup>37</sup> Rule 64B16-26.351(1)-(2), F.A.C.

<sup>38</sup> Rule 64B16-26.351(3)(b), F.A.C.



- Records management and inventory control, including pharmaceutical supplies, medication labeling, medication packaging and storage, controlled substances, and adjudication and billing;
- Interpersonal relations and ethics, including diversity of communications, empathetic communications, ethics governing pharmacy practice, patient and caregiver communications; and
- Pharmaceutical calculations.

The training program must provide the board with educational and professional background of its faculty.<sup>39</sup> A licensed pharmacist or registered pharmacy technician with appropriate expertise must be involved with planning and instruction and must supervise learning experiences.<sup>40</sup>

The board may also review and approve employer-based pharmacy technician training programs. An employer-based program must be offered by a Florida-permitted pharmacy, or affiliated group of pharmacies under common ownership.<sup>41</sup> The program must consist of 160 hours of training over a period of no more than six months and may only be provided to the employees of that pharmacy.<sup>42</sup> The employer-based training program must:<sup>43</sup>

- Meet the same qualifications as required for non-employment based pharmacy technician training programs as indicated above;
- Provide an opportunity for students to evaluate learning experiences, instructional methods, facilitates, and resources;
- Ensure that self-directed learning experience, such as home study or web-based courses, evaluate the participant's knowledge at the completion of the learning experience; and
- Designate a person to assume responsibility for the registered pharmacy technician training program.

### *Scope of Practice*

A registered pharmacy technician may not engage in the practice of the profession of pharmacy; however, a licensed pharmacist may delegate those duties, tasks, and functions that do not fall within the definition of the practice of professional pharmacy.<sup>44</sup> Registered pharmacy technicians' responsibilities include:<sup>45</sup>

- Retrieval of prescription files;
- Data entry;
- Label preparation;
- Counting, weighing, measuring, and pouring of prescription medication;
- Initiation of communication with a prescribing practitioner regarding requests for prescription refill authorization, obtaining clarification on missing or illegible information on prescriptions, and confirmation of information such as names, medication, strength, directions, and refills;

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<sup>39</sup> Rule 64B16-26.351(3)(e), F.A.C.

<sup>40</sup> Id.

<sup>41</sup> Rule 64B16-26.351(4), F.A.C.

<sup>42</sup> Id.

<sup>43</sup> Id.

<sup>44</sup> Section 465.014(1), F.S.

<sup>45</sup> Rule 64B16-27.420(1), F.A.C.

- Acceptance of authorization for prescription renewals; and
- Any other mechanical, technical, or administrative tasks which do not themselves constitute the practice of the profession of pharmacy.

A licensed pharmacist must directly supervise the performance of a registered pharmacy technician,<sup>46</sup> and is responsible for acts performed by persons under his or her supervision.<sup>47</sup> A pharmacist may use technological means to communicate with or observe a registered pharmacy technician who is performing delegated tasks.<sup>48</sup>

The board specifies, by rule, certain acts that registered pharmacy technicians are prohibited from performing:<sup>49</sup>

- Receiving new verbal prescriptions or any change in the medication, strength, or directions of an existing prescription;
- Interpreting a prescription or medication order for therapeutic acceptability and appropriateness;
- Conducting a final verification of dosage and directions;
- Engaging in prospective drug review;
- Monitoring prescription drug usage;
- Transferring a prescription;
- Overriding clinical alerts without first notifying the pharmacist;
- Preparing a copy of a prescription or reading a prescription to any person for the purpose of providing reference concerning treatment of the patient for whom the prescription was written;
- Engaging in patient counseling; or
- Engaging in any other act that requires the exercise of a pharmacist's professional judgment.

A registered pharmacy technicians must wear an identification badge with a designation as a "registered pharmacy technician" and identify herself or himself as a registered pharmacy technician in telephone or other forms of communication.<sup>50</sup>

### ***Pharmacist-to-Technician Ratios***

Florida law prohibits a pharmacist from supervising more than one registered pharmacy technician, unless otherwise permitted by guidelines adopted by the board.<sup>51</sup> The guidelines include the following restrictions:<sup>52</sup>

- A pharmacist engaging in sterile compounding may supervise up to three registered pharmacy technicians.

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<sup>46</sup> Direct supervision means supervision by a pharmacist who is on the premises at all times the delegated tasks are being performed; who is aware of delegated tasks being performed; and who is readily available to provide personal assistance, direction, and approval throughout the time the delegated tasks are being performed (Rule 64B16-27.4001(2)(a), F.A.C.)

<sup>47</sup> Rule 64B16-27.1001(7), F.A.C.

<sup>48</sup> Rule 64B16-27.4001(2)(b), F.A.C.

<sup>49</sup> Rule 64B16-27.420(2), F.A.C.

<sup>50</sup> Rule 64B16-27.100(2), F.A.C.

<sup>51</sup> Section 465.014(1), F.S.

<sup>52</sup> Rule 64B16-27.410, F.A.C.

- A pharmacist who is not engaged in sterile compounding may supervise up to four registered pharmacy technicians.
- In a pharmacy that does not dispense medicinal drugs, a pharmacist may supervise up to six registered pharmacy technicians, as long as the pharmacist or pharmacy is not involved in sterile compounding.
- In a pharmacy that dispenses medicinal drugs in a physically separate area<sup>53</sup> of the pharmacy from which medicinal drugs are not dispensed, a pharmacist may supervise up to six registered pharmacy technicians.

## Telehealth

There is no universally accepted definition of telehealth. In broad terms, telehealth is:

The delivery of health care services, where distance is a critical factor, by all health care professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment<sup>54</sup> and prevention of disease and injuries,<sup>55</sup> research and evaluation, and for the continuing education of health care providers, all in the interests of advancing the health of individuals and their communities.<sup>56</sup>

More specific definitions vary by state and occasionally by profession.<sup>57</sup> There are, however, common elements among the varied definitions of telehealth.

Telehealth generally consists of synchronous and/or asynchronous transmittal of information.<sup>58</sup> Synchronous refers to the live<sup>59</sup> transmission of information between patient and provider during the same time period.<sup>60</sup> Asynchronous telehealth is the transfer of data over a period of time, and

<sup>53</sup> A “physically separate area” is a part of the pharmacy which is separated by a permanent wall or other barrier which restricts access between the two areas.

<sup>54</sup> The University of Florida’s Diabetes Institute utilizes telehealth to deliver treatment to children with diabetes and other endocrine problems who live in Volusia County. This allows the children to receive specialized treatment without the necessity of traveling from Volusia County to Gainesville. The Florida Department of Health’s Children’s Medical Services underwrites the program. See <https://ufhealth.org/diabetes-center-excellence/telemedicine> (last visited on Feb. 1, 2018).

<sup>55</sup> The University of South Florida has partnered with American Well to provide health care services to the residents of the Villages via telehealth. The goal is to reduce hospital admissions, readmission rates, and pharmacy costs, while maintaining Medicare beneficiaries in their homes rather than long-term care settings. See <http://hscweb3.hsc.usf.edu/blog/2012/06/22/usf-health-and-american-well-to-bring-telehealth-to-seniors-living-at-the-villages/> (last visited on Feb. 1, 2018).

<sup>56</sup> World Health Organization, *Telemedicine: Opportunities and Developments in Member States*, Global Observatory for Ehealth Series- Volume 2, Section 1.2, page 9 (2010), available at [http://apps.who.int/iris/bitstream/10665/44497/1/9789241564144\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/44497/1/9789241564144_eng.pdf) (last visited on Feb. 1, 2018).

<sup>57</sup> Center for Connected Health Policy, The National Telehealth Policy Resource Center, *State Telehealth Laws and Medicaid Program Policies* (August 2016), available at [http://www.cchpca.org/sites/default/files/resources/50%20STATE%20COMPLETE%20REPORT%20PASSWORD%20AUG%202016\\_1.pdf](http://www.cchpca.org/sites/default/files/resources/50%20STATE%20COMPLETE%20REPORT%20PASSWORD%20AUG%202016_1.pdf) (last visited on Feb. 1, 2018)

<sup>58</sup> The majority of telehealth definitions allow for both synchronous and asynchronous transmittal of information. Some definitions however omit asynchronous from the definition of telehealth.

<sup>59</sup> This is also referred to as “real time” or “interactive” telehealth.

<sup>60</sup> American Telemedicine Association, *Telemedicine Glossary*, available at <http://thesource.americantelemed.org/resources/telemedicine-glossary> (last visited on Feb. 1, 2018). The use of live video to evaluate and diagnosis a patient would be considered synchronous telehealth.

typically in separate time frames.<sup>61</sup> This is commonly referred to as “store and forward.” Definitions of telehealth also commonly contain restrictions related to the location where telehealth may be used. For example, the use of the “hub and spoke” model is a common location restriction. A hub site is the location from which specialty or consultative services originate, i.e., the provider.<sup>62</sup> A spoke site is a remote site where the patient is presented during the telehealth encounter.<sup>63</sup> Under this model, health services may be provided through telehealth only if the patient is located at a designated spoke site and the provider is located at a designated hub site.

Telehealth is not a type of health care service but rather is a mechanism for delivery of health care services. Health care professionals use telehealth as a platform to provide traditional health care services in a non-traditional manner. These services include, among others, preventative medicine and the treatment of chronic conditions.<sup>64</sup>

### ***Telepharmacy***

Telepharmacy is the provision of pharmaceutical care by pharmacies and pharmacists through the use of telepharmacy technologies to patients or their agents at a distance.<sup>65</sup> Telepharmacy operations include, but are not limited to, drug review and monitoring, dispensing of medications, medication therapy management, clinical consultation, and patient counseling.<sup>66</sup>

In 2001, North Dakota became the first state to regulate telepharmacy.<sup>67</sup> North Dakota created a pilot project using telepharmacy to save rural pharmacies from closing and to provide telepharmacy services to underserved rural communities in that state.<sup>68</sup> The pilot project authorized community pharmacies to open and operate telepharmacy sites in rural communities without a pharmacist being physically present to supervise a registered pharmacy technician working at the remote site.<sup>69</sup> A pharmacist supervises the pharmacy technician and speaks with

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<sup>61</sup> Id. A common example of synchronous telehealth is the transfer of X-rays or MRI images from one health care provider to another health care provider for review in the future.

<sup>62</sup> Id.

<sup>63</sup> Id.

<sup>64</sup> U.S. Department of Health and Human Services, Report to Congress: E-Health and Telemedicine, (August 2016), available at <https://aspe.hhs.gov/system/files/pdf/206751/TelemedicineE-HealthReport.pdf> (last visited Feb. 1, 2018).

<sup>65</sup> National Association of Boards of Pharmacy, “Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy,” (Aug. 2017), available at <https://nabp.pharmacy/publications-reports/resource-documents/model-pharmacy-act-rules/> (last visited Feb. 1, 2018). Telepharmacy technologies means secure electronic communications, information exchange, or other methods that meet state and federal requirements.

<sup>66</sup> E. Alexander et al, ASHP Statement on Telepharmacy, 74 Am J Health-System Pharm., e236 (May 2017), available at <http://www.ajhp.org/content/74/9/e236?sso-checked=true> (last visited Feb. 1, 2018).

<sup>67</sup> George Tzanetakos et al, RUPRI Center for Rural Health Policy Analysis, University of Iowa College of Public Health, Rural Policy Brief: Telepharmacy Rules and Statutes: A 50-State Survey, Brief No. 2017-4, (April 2017), available at <https://www.public-health.uiowa.edu/rupri/publications/policybriefs/2017/Telepharmacy%20Rules%20and%20Statutes.pdf> (last visited Feb. 1, 2018).

<sup>68</sup> Daniel L. Friesner et al, Do Remote Community Telepharmacies Have Higher Medication Error Rates than Traditional Community Pharmacies? Evidence from the North Dakota Telepharmacy Project, 51 J Am Pharm Assoc., 580 (Sept./Oct. 2011), available at [https://www.ndsu.edu/fileadmin/telepharmacy/APhA\\_article\\_2011\\_-\\_Copy.pdf](https://www.ndsu.edu/fileadmin/telepharmacy/APhA_article_2011_-_Copy.pdf) (last visited Feb. 1, 2018).

<sup>69</sup> Id at 582.

patients using real-time communications technology.<sup>70</sup> Almost 80,000 rural citizens had pharmacy services established, restored, or retained under the pilot project.<sup>71</sup>

At least 23 states have enacted laws or regulations that allow for the use of telepharmacy and/or remote dispensing since 2001.<sup>72</sup> The regulation of telepharmacy and remote dispensing varies by state. Some states geographically limit the provision of telepharmacy services to ensure that remote dispensing sites are only established in rural areas or medically underserved areas<sup>73</sup> while others restrict it by facility type such as rural health centers.<sup>74</sup> Many states have included minimum staffing and education requirements, such as requiring a minimum level of experience for the pharmacy technicians or limiting the number of pharmacy technicians that a pharmacist may supervise.<sup>75</sup>

### III. Effect of Proposed Changes:

**Section 1** amends s. 465.003, F.S., to define an RDSP to include every location where medicinal drugs are prepared by a registered pharmacy technician who is electronically supervised by an offsite pharmacist and dispensed pursuant to s. 465.014(1), F.S., to the patient after verification, certification, and counseling by the pharmacist. The bill exempts RDSPs from the requirement to close when a pharmacist is not present and on duty if the pharmacist is remotely supervising a registered pharmacy technician at an RDSP.

**Section 2** amends s. 465.014(1), F.S., to allow a registered pharmacy technician to dispense medicinal drugs when operating under electronic supervision of an offsite Florida licensed pharmacist at an RDSP.

**Section 3** amends s. 465.015, F.S., to exempt any person who owns, operates, maintain, opens, establishes, conducts, or has charge of an RDSP from the requirement that a licensed pharmacist or intern is required to fill, compound, or dispense any prescription or medicinal drugs. The bill also exempts registered pharmacy technicians working in an RDSP from the restriction on dispensing medicinal medications without an active pharmacist's license or without being a registered pharmacy intern.

**Section 4** creates s. 465.0198, F.S., to allow for the operation of RDSPs. The bill:

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<sup>70</sup> Id.

<sup>71</sup> National Association of Boards of Pharmacy, Telepharmacy: The New Frontier of Patient Care and Professional Practice, 46 Innovations 46 (June/July 2017), available at [https://nabp.pharmacy/wp-content/uploads/2016/07/Innovations\\_June\\_July\\_Final.pdf](https://nabp.pharmacy/wp-content/uploads/2016/07/Innovations_June_July_Final.pdf) (last visited Feb.1, 2018).

<sup>72</sup> Supra note 678. These states include Alaska, Colorado, Hawaii, Idaho, Illinois, Indiana, Iowa, Louisiana, Minnesota, Montana, Nebraska, Nevada, New Mexico, North Dakota, Oregon, South Dakota, Tennessee, Texas, Utah, Vermont, West Virginia, Wisconsin, and Wyoming.

<sup>73</sup> Id. For example, Colorado requires that a telepharmacy outlet be more than 20 miles from the nearest prescription drug outlet or another telepharmacy outlet. (Colo. Rev. Stat. s. 12-12.5-102 (2017)).

<sup>74</sup> Id. For example, Wisconsin limits the operation of a remote dispensing site to a health care facility, office or clinic of a practitioner, county jail, rehabilitation facility, state prison, county house of correction, juvenile correctional facility, juvenile detention center, or residential care center for children and youth. (Wis. Admin. Code s. Phar. 7.095(3)).

<sup>75</sup> Id. For example, Illinois requires a pharmacy technician to have at least one year of experience and prohibits a pharmacist from supervising more than three sites that are simultaneously open. (Ill. Admin. Code tit. 68, s. 1330.510).

- Requires any person desiring to operate an RDSP to apply to the DOH for a permit. To receive a permit the application must comply with the laws and board rules governing pharmacy and must designate a licensed pharmacist or consultant pharmacist as the prescription department manager responsible for oversight of the RDSP. The bill requires an RDSP to notify the DOH within 10 days if the prescription department manager changes.
- Requires an RDSP to pass an onsite inspection before receiving an initial permit or changing locations. The DOH is required to inspect the RDSP within 90 days before issuing the permit.
- Establishes requirements for an RDSP, including that:
  - An RDSP be jointly owned, or operated under contract with, a supervising pharmacy. A “supervising pharmacy” is defined as a licensed pharmacy in Florida that employs a Florida licensed pharmacist who remotely supervises the registered pharmacy technician at the RDSP.
  - An RDSP must be under 24-hour video surveillance, display a sign indicating that the RDSP is an RDSP and is under video surveillance, and must keep video surveillance recordings for at least 45 days.
  - An RDSP must be located in a rural area<sup>76</sup> and at least 10 miles from an existing community pharmacy unless the RDSP is located in a hospital or a clinic. For the purposes of this requirement a “clinic” is defined as an entity where health care services are provided to individuals and which tenders charges for reimbursement for such services, excluding a mobile clinic and a portable equipment provider. The bill specifies that an RDSP may not lose its permit if a community pharmacy opens within 10 miles of the RDSP subsequent to the RDSP opening.
  - The prescription department manager or other pharmacist employed by the supervising pharmacy visits the RDSP on a schedule determined by the board to inspect the pharmacy, address personnel matters, and provide clinic services for patients.
  - A registered pharmacy technician must have completed at least 2,080 hours of experience at a pharmacy within the two years immediately preceding the date on which the registered pharmacy technician begins employment at the RDSP.
- Allows an RDSP to store, hold, and dispense all medicinal drugs<sup>77</sup> including schedule III-V controlled substances listed in s. 893.03(3)-(5), F.S.
- Restricts an RDSP from storing, holding, or dispensing schedule II narcotic controlled substances and performing centralized prescription filling;<sup>78</sup>
- Restricts a registered pharmacy intern from performing sterile or complex nonsterile compounding;
- Requires an RDSP to maintain a policy and procedures manual that must be made available to the board upon request. The manual must include:
  - A description of how the RDSP will comply with federal and state laws, rules, and regulations.
  - The procedure for supervising the RDSP and counseling its patients before the dispensing of any medicinal drug.

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<sup>76</sup> As defined in s. 381.0406, F.S. A map of rural counties is available at <http://www.floridahealth.gov/programs-and-services/community-health/rural-health/documents/ruralcountiespdf.12.pdf>. (Last visited on Feb. 6, 2018).

<sup>77</sup> Supra note 1

<sup>78</sup> Supra note 2

- The procedure for reviewing the prescription drug inventory and drug records maintained by the RDSP.
- The policy and procedure for providing appropriate security to protect the confidentiality and integrity of patient information.
- The written plan for recovery from an event that interrupts or prevents the pharmacist from supervising the RDSP's operation.
- The procedure by which the supervising pharmacist consults the state prescription drug monitoring program (PDMP) before authorizing any controlled substance for dispensing and reports the dispensing of controlled substances to the PDMP.
- The specific duties, tasks, and functions that a registered pharmacy technician is authorized to perform at the RDSP.

**Section 5** amends s. 460.022, F.S., to allow a Florida licensed pharmacist to serve as a prescription manager for up to two RDSPs that are under common control and to make a technical change.

**Section 6** amends s. 465.0265, F.S., to conform its provisions to the restriction on RDSPs performing centralized prescription filling.

**Section 7** establishes an effective date of July 1, 2018.

#### **IV. Constitutional Issues:**

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

#### **V. Fiscal Impact Statement:**

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

CS/SB 848 may have an indeterminate fiscal impact on persons who open and run an RDSP pursuant to the provisions of the bill. It may also have an indeterminate fiscal impact on community pharmacies that are nearby, but beyond the 10-mile zone.

C. **Government Sector Impact:**

CS/SB 848 may have an indeterminate fiscal impact on the DOH related to establishing the RDSP permit and regulating permitted RDSPs.

VI. **Technical Deficiencies:**

None.

VII. **Related Issues:**

Lines 158-162 of the bill specify that a RDSP may store, hold, and dispense medicinal drugs listed as a controlled substance in schedules III-V but may not store, hold, and dispense narcotic controlled substances listed in schedule II. The bill does not specify whether an RDSP may store, hold, and dispense nonnarcotic schedule II controlled substances. The bill should be clarified to specify whether an RDSP may or may not store, hold, and dispense nonnarcotic controlled substances listed in schedule II.

Lines 201-203 of the bill restrict a registered pharmacy technician working in an RDSP from performing sterile and complex nonsterile compounding. The use of the term “complex” nonsterile compounding implies that a pharmacy technician may perform noncomplex nonsterile compounding at an RDSP. However, it is unclear what the definitions of “complex” and “noncomplex” nonsterile compounding include. The bill should be amended to clarify what compounding, if any, a registered pharmacy technician is authorized to perform at an RDSP.

VIII. **Statutes Affected:**

This bill substantially amends the following sections of the Florida Statutes: 465.003, 465.014, 465.015, 465.022, and 465.0265.

This bill creates section 465.0198 of the Florida Statutes.

IX. **Additional Information:**

A. **Committee Substitute – Statement of Substantial Changes:**

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

**CS by Health Policy on February 6, 2018:**

The CS changes the title of the bill to Telepharmacy and:

- Tightens the regulation of RDSPs by:
  - Requiring that RDSPs be supervised by Florida licensed pharmacists;
  - Restricting a pharmacy technician at an RDSP from performing sterile or complex nonsterile compounding;
  - Restricting a pharmacy technician at an RDSP from dispensing narcotic drugs listed as a schedule II controlled substance; and
  - Requiring a registered pharmacy technician who works in a RDSP to have certain experience.



- Requires all RDSPs to be located in rural areas (as defined in s. 381.0406, F.S.) and be located at least 10 miles from an existing community pharmacy unless the RDSP is located in a hospital or a clinic.
- Requires each RDSP to be inspected by the DOH before being issued an initial permit or a permit for a change of location.
- Specifies that the section establishing RDSPs does not alter supervisory requirements for pharmacy technicians.
- Removes the provision that an RDSP may not be counted toward network adequacy in managed care programs.
- Makes a number of technical changes to clean up the bill's provisions.

**B. Amendments:**

None.



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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
02/06/2018	.	
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The Committee on Health Policy (Grimsley) recommended the following:

**Senate Amendment (with title amendment)**

Delete everything after the enacting clause  
and insert:

Section 1. Subsection (11) of section 465.003, Florida  
Statutes, is amended to read:

465.003 Definitions.—As used in this chapter, the term:

(11) (a) "Pharmacy" includes a community pharmacy, an  
institutional pharmacy, a nuclear pharmacy, a special pharmacy,  
~~and~~ an Internet pharmacy, and a remote dispensing site pharmacy.



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11           1. The term "community pharmacy" includes every location  
12 where medicinal drugs are compounded, dispensed, stored, or sold  
13 or where prescriptions are filled or dispensed on an outpatient  
14 basis.

15           2. The term "institutional pharmacy" includes every  
16 location in a hospital, clinic, nursing home, dispensary,  
17 sanitarium, extended care facility, or other facility,  
18 hereinafter referred to as "health care institutions," where  
19 medicinal drugs are compounded, dispensed, stored, or sold.

20           3. The term "nuclear pharmacy" includes every location  
21 where radioactive drugs and chemicals within the classification  
22 of medicinal drugs are compounded, dispensed, stored, or sold.  
23 The term "nuclear pharmacy" does not include hospitals licensed  
24 under chapter 395 or the nuclear medicine facilities of such  
25 hospitals.

26           4. The term "special pharmacy" includes every location  
27 where medicinal drugs are compounded, dispensed, stored, or sold  
28 if such locations are not otherwise defined in this subsection.

29           5. The term "Internet pharmacy" includes locations not  
30 otherwise licensed or issued a permit under this chapter, within  
31 or outside this state, which use the Internet to communicate  
32 with or obtain information from consumers in this state and use  
33 such communication or information to fill or refill  
34 prescriptions or to dispense, distribute, or otherwise engage in  
35 the practice of pharmacy in this state. Any act described in  
36 this definition constitutes the practice of pharmacy as defined  
37 in subsection (13).

38           6. The term "remote dispensing site pharmacy" includes  
39 every location where medicinal drugs are prepared by a



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40 registered pharmacy technician who is electronically supervised  
41 by an offsite pharmacist and dispensed pursuant to s. 465.014(1)  
42 to the patient after verification, certification, and counseling  
43 by the pharmacist.

44 (b) The pharmacy department of any permittee shall be  
45 considered closed whenever a Florida licensed pharmacist is not  
46 present and on duty. The term "not present and on duty" may  
47 ~~shall~~ not be construed to prevent:

48 1. A pharmacist from exiting the prescription department  
49 for the purposes of consulting or responding to inquiries or  
50 providing assistance to patients or customers;~~;~~

51 2. A pharmacist attending to personal hygiene needs;~~;~~~~or~~

52 3. A pharmacist performing any other function for which the  
53 pharmacist is responsible, provided that such activities are  
54 conducted in a manner consistent with the pharmacist's  
55 responsibility to provide pharmacy services; or

56 4. An offsite pharmacist from remotely supervising a  
57 registered pharmacy technician at a remote dispensing site  
58 pharmacy.

59 Section 2. Subsection (1) of section 465.014, Florida  
60 Statutes, is amended to read:

61 465.014 Pharmacy technician.—

62 (1) A person other than a licensed pharmacist or pharmacy  
63 intern may not engage in the practice of the profession of  
64 pharmacy, except that a licensed pharmacist may delegate to  
65 pharmacy technicians who are registered pursuant to this section  
66 those duties, tasks, and functions that do not fall within the  
67 purview of s. 465.003(13). However, a registered pharmacy  
68 technician may dispense medicinal drugs when operating under the



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69 electronic supervision of an offsite Florida licensed pharmacist  
70 pursuant to s. 465.0198. All such delegated acts must be  
71 performed under the direct supervision of a licensed pharmacist  
72 who is responsible for all such acts performed by persons under  
73 his or her supervision. A registered pharmacy technician, under  
74 the supervision of a pharmacist, may initiate or receive  
75 communications with a practitioner or his or her agent, on  
76 behalf of a patient, regarding refill authorization requests. A  
77 licensed pharmacist may not supervise more than one registered  
78 pharmacy technician unless otherwise permitted by the guidelines  
79 adopted by the board. The board shall establish guidelines to be  
80 followed by licensees or permittees in determining the  
81 circumstances under which a licensed pharmacist may supervise  
82 more than one pharmacy technician.

83 Section 3. Subsections (1) and (2) of section 465.015,  
84 Florida Statutes, are amended to read:

85 465.015 Violations and penalties.—

86 (1) It is unlawful for any person to own, operate,  
87 maintain, open, establish, conduct, or have charge of, either  
88 alone or with another person or persons, a pharmacy:

89 (a) Which is not registered under ~~the provisions of this~~  
90 chapter.

91 (b) In which a person not licensed as a pharmacist in this  
92 state or not registered as an intern in this state or in which  
93 an intern who is not acting under the direct and immediate  
94 personal supervision of a licensed pharmacist fills, compounds,  
95 or dispenses any prescription or dispenses medicinal drugs. This  
96 paragraph does not apply to any person who owns, operates,  
97 maintains, opens, establishes, conducts, or has charge of a



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98 remote dispensing site pharmacy pursuant to s. 465.0198.

99 (2) It is unlawful for any person:

100 (a) To make a false or fraudulent statement, either for  
101 herself or himself or for another person, in any application,  
102 affidavit, or statement presented to the board or in any  
103 proceeding before the board.

104 (b) To fill, compound, or dispense prescriptions or to  
105 dispense medicinal drugs if such person does not hold an active  
106 license as a pharmacist in this state, is not registered as an  
107 intern in this state, or is an intern not acting under the  
108 direct and immediate personal supervision of a licensed  
109 pharmacist. This paragraph does not apply to a registered  
110 pharmacy technician dispensing medicinal drugs pursuant to s.  
111 465.0198.

112 (c) To sell or dispense drugs as defined in s. 465.003(8)  
113 without first being furnished with a prescription.

114 (d) To sell samples or complimentary packages of drug  
115 products.

116 Section 4. Section 465.0198, Florida Statutes, is created  
117 to read:

118 465.0198 Remote dispensing site pharmacy permits.-

119 (1) Any person desiring a permit to operate a remote  
120 dispensing site pharmacy must apply to the department for a  
121 remote dispensing site pharmacy permit. If the board certifies  
122 that the application complies with the laws and board rules  
123 governing the practice of the profession of pharmacy, the  
124 department must issue the permit. A permit may not be issued  
125 unless a licensed pharmacist or consultant pharmacist is  
126 designated as the prescription department manager responsible



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127 for the oversight of the remote dispensing site pharmacy. The  
128 permittee must notify the department within 10 days after any  
129 change of the prescription department manager.

130 (2) As a prerequisite to issuance of an initial permit or a  
131 permit for a change of location, the remote dispensing site  
132 pharmacy must pass an onsite inspection. The department must  
133 make the inspection within 90 days before issuance of the  
134 permit.

135 (3) The remote dispensing site pharmacy must:

136 (a) Be jointly owned by a supervising pharmacy or operated  
137 under a contract with a supervising pharmacy. For purposes of  
138 this subsection, "supervising pharmacy" means a licensed  
139 pharmacy in this state which employs a Florida licensed  
140 pharmacist who remotely supervises a registered pharmacy  
141 technician at a remote dispensing site pharmacy.

142 (b) Display a sign visible to the public indicating that  
143 the location is a remote dispensing site pharmacy and that the  
144 facility is under 24-hour video surveillance. The remote  
145 dispensing site pharmacy must retain the video surveillance  
146 recordings for at least 45 days.

147 (c) Be located in an area defined as rural pursuant to s.  
148 381.0406 and be at least 10 miles from an existing community  
149 pharmacy, unless the remote dispensing site pharmacy is located  
150 in a hospital licensed under chapter 395 or in a clinic. For  
151 purposes of this paragraph, the term "clinic" means an entity  
152 where health care services are provided to individuals and which  
153 tenders charges for reimbursement for such services, excluding a  
154 mobile clinic and a portable equipment provider.

155 (4) A remote dispensing site pharmacy may not lose its



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156 permit based on the subsequent opening of a community pharmacy  
157 within 10 miles of the remote dispensing site pharmacy.

158 (5) A remote dispensing site pharmacy may store, hold, and  
159 dispense all medicinal drugs including those listed in s.  
160 893.03(3)-(5). A remote dispensing pharmacy may not store, hold,  
161 or dispense narcotic controlled substances listed in s.  
162 893.03(2).

163 (6) A remote dispensing site pharmacy may not perform  
164 centralized prescription filling, as defined in s. 465.003(16).

165 (7) A remote dispensing site pharmacy must maintain a  
166 policy and procedures manual, which shall be made available to  
167 the board or its agent upon request. The policy and procedures  
168 manual shall include:

169 (a) A description of how the pharmacy will comply with  
170 federal and state laws, rules, and regulations.

171 (b) The procedure for supervising the remote dispensing  
172 site pharmacy and counseling its patients before the dispensing  
173 of any medicinal drug pursuant to this section.

174 (c) The procedure for reviewing the prescription drug  
175 inventory and drug records maintained by the remote dispensing  
176 site pharmacy.

177 (d) The policy and procedure for providing appropriate  
178 security to protect the confidentiality and integrity of patient  
179 information.

180 (e) The written plan for recovery from an event that  
181 interrupts or prevents the pharmacist from supervising the  
182 remote dispensing site pharmacy's operation.

183 (f) The procedure by which a supervising pharmacist  
184 consults the state prescription drug monitoring program before





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185 authorizing any controlled substance for dispensing and reports  
186 the dispensing of a controlled substance as required under s.  
187 893.055.

188 (g) The specific duties, tasks, and functions that a  
189 registered pharmacy technician is authorized to perform at the  
190 remote dispensing site pharmacy.

191 (8) The prescription department manager or other pharmacist  
192 employed by the supervising pharmacy must visit the remote  
193 dispensing site pharmacy, based on a schedule designated by the  
194 board, to inspect the pharmacy, address personnel matters, and  
195 provide clinical services for patients.

196 (9) A registered pharmacy technician must have completed at  
197 least 2,080 hours of experience at a pharmacy within the 2 years  
198 immediately preceding the date on which the registered pharmacy  
199 technician begins employment at the remote dispensing site  
200 pharmacy.

201 (10) A registered pharmacy technician working at a remote  
202 dispensing site pharmacy may not perform sterile or complex  
203 nonsterile compounding.

204 (11) This section does not alter the supervision  
205 requirements established in s. 465.014.

206 Section 5. Paragraph (c) of subsection (11) of section  
207 465.022, Florida Statutes, is amended to read:

208 465.022 Pharmacies; general requirements; fees.—

209 (11) A permittee must notify the department of the identity  
210 of the prescription department manager within 10 days after  
211 employment. The prescription department manager must comply with  
212 the following requirements:

213 (c) A Florida licensed ~~registered~~ pharmacist may not serve



214 as the prescription department manager in more than one location  
215 unless approved by the board. However, a Florida licensed  
216 pharmacist may serve as a prescription department manager for no  
217 more than two remote dispensing site pharmacies, if such  
218 pharmacies are under common control.

219 Section 6. Subsection (1) of section 465.0265, Florida  
220 Statutes, is amended to read:

221 465.0265 Centralized prescription filling.—

222 (1) Except as otherwise provided in this chapter, a  
223 pharmacy licensed under this chapter may perform centralized  
224 prescription filling for another pharmacy, provided that the  
225 pharmacies have the same owner or have a written contract  
226 specifying the services to be provided by each pharmacy, the  
227 responsibilities of each pharmacy, and the manner in which the  
228 pharmacies will comply with federal and state laws, rules, and  
229 regulations.

230 Section 7. This act shall take effect July 1, 2018.

231  
232 ===== T I T L E A M E N D M E N T =====

233 And the title is amended as follows:

234 Delete everything before the enacting clause  
235 and insert:

236 A bill to be entitled  
237 An act relating to telepharmacy; amending s. 465.003,  
238 F.S.; revising and providing definitions; amending s.  
239 465.014, F.S.; authorizing a registered pharmacy  
240 technician to dispense medicinal drugs under certain  
241 conditions; amending s. 465.015, F.S.; conforming  
242 provisions to changes made by the act; creating s.



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243 465.0198, F.S.; providing permit requirements for  
244 remote dispensing site pharmacies; providing operating  
245 requirements and prohibitions for a remote dispensing  
246 site pharmacy; defining the term "clinic"; requiring  
247 the prescription department manager or other  
248 pharmacist employed by the supervising pharmacy to  
249 visit the remote dispensing site pharmacy; providing  
250 an experience requirement for a registered pharmacy  
251 technician working at a remote site pharmacy;  
252 prohibiting a registered pharmacy technician from  
253 performing sterile or nonsterile compounding;  
254 providing construction; amending s. 465.022, F.S.;  
255 authorizing a Florida licensed pharmacist to serve as  
256 the prescription drug manager at more than one remote  
257 dispensing site pharmacy under certain conditions;  
258 amending s. 465.0265, F.S.; conforming provisions to  
259 changes made by the act; providing an effective date.

By Senator Grimsley

26-00972-18

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1                                   A bill to be entitled  
2       An act relating to remote dispensing site pharmacies;  
3       amending s. 465.003, F.S.; redefining the term  
4       "pharmacy" to include remote dispensing site  
5       pharmacies; providing that an offsite pharmacist who  
6       supervises a registered pharmacy technician at a  
7       remote dispensing site is not considered to be not  
8       present or off duty; amending s. 465.014, F.S.;  
9       authorizing registered pharmacy technicians to  
10      compound and dispense medicinal drugs when operating  
11      under the electronic supervision of an offsite  
12      pharmacist; amending s. 465.015, F.S.; conforming  
13      provisions to changes made by the act; creating s.  
14      465.0198, F.S.; providing permit requirements for  
15      remote dispensing site pharmacies; providing a  
16      permitting process for such pharmacies; providing  
17      requirements for such pharmacies; providing that such  
18      pharmacies are not considered pharmacy locations for  
19      certain purposes; authorizing such pharmacies to  
20      store, hold, and dispense medicinal drugs; prohibiting  
21      such pharmacies from performing centralized  
22      prescription filling; requiring such pharmacies to  
23      maintain a policy and procedures manual that includes  
24      specified information; amending s. 465.022, F.S.;  
25      authorizing a registered pharmacist to serve as the  
26      prescription department manager at up to a specified  
27      number of remote dispensing site pharmacies under  
28      certain conditions; amending s. 465.0265, F.S.;  
29      conforming a provision to changes made by the act;

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30 providing an effective date.

31  
32 Be It Enacted by the Legislature of the State of Florida:

33  
34 Section 1. Subsection (11) of section 465.003, Florida  
35 Statutes, is amended to read:

36 465.003 Definitions.—As used in this chapter, the term:

37 (11) (a) "Pharmacy" includes a community pharmacy, an  
38 institutional pharmacy, a nuclear pharmacy, a special pharmacy,  
39 ~~and~~ an Internet pharmacy, and a remote dispensing site pharmacy.

40 1. The term "community pharmacy" includes every location  
41 where medicinal drugs are compounded, dispensed, stored, or sold  
42 or where prescriptions are filled or dispensed on an outpatient  
43 basis.

44 2. The term "institutional pharmacy" includes every  
45 location in a hospital, clinic, nursing home, dispensary,  
46 sanitarium, extended care facility, or other facility,  
47 hereinafter referred to as "health care institutions," where  
48 medicinal drugs are compounded, dispensed, stored, or sold.

49 3. The term "nuclear pharmacy" includes every location  
50 where radioactive drugs and chemicals within the classification  
51 of medicinal drugs are compounded, dispensed, stored, or sold.  
52 The term "nuclear pharmacy" does not include hospitals licensed  
53 under chapter 395 or the nuclear medicine facilities of such  
54 hospitals.

55 4. The term "special pharmacy" includes every location  
56 where medicinal drugs are compounded, dispensed, stored, or sold  
57 if such locations are not otherwise defined in this subsection.

58 5. The term "Internet pharmacy" includes locations not

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59 otherwise licensed or issued a permit under this chapter, within  
60 or outside this state, which use the Internet to communicate  
61 with or obtain information from consumers in this state and use  
62 such communication or information to fill or refill  
63 prescriptions or to dispense, distribute, or otherwise engage in  
64 the practice of pharmacy in this state. Any act described in  
65 this definition constitutes the practice of pharmacy as defined  
66 in subsection (13).

67 6. The term "remote dispensing site pharmacy" includes  
68 every location where medicinal drugs are compounded or dispensed  
69 by a registered pharmacy technician who is electronically  
70 supervised by an offsite pharmacist and which is overseen by a  
71 prescription department manager.

72 (b) The pharmacy department of any permittee is ~~shall be~~  
73 considered closed whenever a ~~Florida-licensed~~ pharmacist is not  
74 present and on duty. The term "not present and on duty" may  
75 ~~shall~~ not be construed to prevent:

76 1. A pharmacist from exiting the prescription department  
77 for the purposes of:

78 a. Consulting or responding to inquiries or providing  
79 assistance to patients or customers;~~IT~~

80 b. Attending to personal hygiene needs;~~IT~~ or

81 c. Performing any other function for which the pharmacist  
82 is responsible, provided that such activities are conducted in a  
83 manner consistent with the pharmacist's responsibility to  
84 provide pharmacy services.

85 2. An offsite pharmacist from electronically supervising a  
86 registered pharmacy technician at a remote dispensing site  
87 pharmacy.

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88 Section 2. Subsection (1) of section 465.014, Florida  
89 Statutes, is amended to read:

90 465.014 Pharmacy technician.—

91 (1) A person other than a licensed pharmacist or pharmacy  
92 intern may not engage in the practice of the profession of  
93 pharmacy, however:

94 (a) except that A licensed pharmacist may delegate to  
95 pharmacy technicians who are registered pursuant to this section  
96 those duties, tasks, and functions that do not fall within the  
97 purview of s. 465.003(13). All such delegated acts must be  
98 performed under the direct supervision of a licensed pharmacist  
99 who is responsible for all such acts performed by persons under  
100 his or her supervision.

101 (b) A registered pharmacy technician who is registered  
102 pursuant to this section may compound and dispense medicinal  
103 drugs when operating under the electronic supervision of an  
104 offsite pharmacist pursuant to s. 465.0198.

105  
106 A registered pharmacy technician, under the supervision of a  
107 pharmacist, may initiate or receive communications with a  
108 practitioner or his or her agent, on behalf of a patient,  
109 regarding refill authorization requests. A licensed pharmacist  
110 may not supervise more than one registered pharmacy technician  
111 unless otherwise permitted by the guidelines adopted by the  
112 board. The board shall establish guidelines to be followed by  
113 licensees or permittees in determining the circumstances under  
114 which a licensed pharmacist may supervise more than one pharmacy  
115 technician.

116 Section 3. Subsections (1) and (2) of section 465.015,

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117 Florida Statutes, are amended to read:

118 465.015 Violations and penalties.—

119 (1) It is unlawful for any person to own, operate,  
120 maintain, open, establish, conduct, or have charge of, either  
121 alone or with another person or persons, a pharmacy:

122 (a) Which is not registered under the provisions of this  
123 chapter.

124 (b) In which a person not licensed as a pharmacist in this  
125 state or not registered as an intern in this state or in which  
126 an intern who is not acting under the direct and immediate  
127 personal supervision of a licensed pharmacist fills, compounds,  
128 or dispenses any prescription or dispenses medicinal drugs. This  
129 paragraph does not apply to any person who owns, operates,  
130 maintains, opens, establishes, conducts, or has charge of a  
131 remote dispensing site pharmacy pursuant to s. 465.0198.

132 (2) It is unlawful for any person:

133 (a) To make a false or fraudulent statement, either for  
134 herself or himself or for another person, in any application,  
135 affidavit, or statement presented to the board or in any  
136 proceeding before the board.

137 (b) To fill, compound, or dispense prescriptions or to  
138 dispense medicinal drugs if such person does not hold an active  
139 license as a pharmacist in this state, is not registered as an  
140 intern in this state, or is an intern not acting under the  
141 direct and immediate personal supervision of a licensed  
142 pharmacist. This paragraph does not apply to a registered  
143 pharmacy technician preparing or dispensing medicinal drugs  
144 pursuant to s. 465.0198.

145 (c) To sell or dispense drugs as defined in s. 465.003(8)



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146 without first being furnished with a prescription.

147 (d) To sell samples or complimentary packages of drug  
148 products.

149 Section 4. Section 465.0198, Florida Statutes, is created  
150 to read:

151 465.0198 Remote dispensing site pharmacy permits.-

152 (1) Any person desiring a permit to operate a remote  
153 dispensing site pharmacy shall apply to the department for a  
154 remote dispensing site pharmacy permit. If the board certifies  
155 that the application complies with the laws and rules of the  
156 board governing the practice of the profession of pharmacy, the  
157 department must issue the permit. A permit may not be issued  
158 unless a pharmacist is designated as the prescription department  
159 manager responsible for the oversight of the remote dispensing  
160 site pharmacy.

161 (2) A remote dispensing site pharmacy must:

162 (a) Be jointly owned by a supervising pharmacy or operated  
163 under a contract with a supervising pharmacy. For purposes of  
164 this subsection, "supervising pharmacy" means a pharmacy  
165 licensed under this chapter which employs a pharmacist who  
166 remotely supervises a registered pharmacy technician at a remote  
167 dispensing site pharmacy.

168 (b) Display a sign visible to the public indicating that  
169 the location is a remote dispensing site pharmacy and that the  
170 facility is under 24-hour video surveillance. The remote  
171 dispensing site pharmacy must retain the video surveillance  
172 recordings for at least 45 days after the date they are  
173 recorded.

174 (c) Be located at least 10 miles from an existing community

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175 pharmacy, unless:

176 1. The applicant for the proposed remote dispensing site  
177 pharmacy demonstrates to the board that the proposed remote  
178 dispensing site pharmacy will promote public health without  
179 unduly harming an existing community pharmacy located within the  
180 10-mile radius;

181 2. The community pharmacy that is located within the 10-  
182 mile radius from the remote dispensing site pharmacy is an  
183 institutional pharmacy; or

184 3. A community pharmacy opens within 10 miles of an  
185 existing remote dispensing site pharmacy.

186 (d) Ensure that the prescription department manager visits  
187 the remote dispensing site pharmacy on a schedule determined by  
188 the board to inspect the pharmacy and address personnel matters.

189 (e) Provide clinical services for patients and must notify  
190 the department within 10 days after any change in the employment  
191 of the prescription department manager.

192 (3) A remote dispensing site pharmacy is not considered a  
193 pharmacy location for purposes of network access in managed care  
194 programs.

195 (4) A remote dispensing site pharmacy may store, hold, and  
196 dispense all medicinal drugs including those listed in s.  
197 893.03.

198 (5) A remote dispensing site pharmacy may not perform  
199 centralized prescription filling, as defined in s. 465.003(16).

200 (6) A remote dispensing site pharmacy must maintain a  
201 policy and procedures manual, which shall be made available to  
202 the board or its agent upon request. The policy and procedures  
203 manual must include:

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204       (a) A description of how the remote dispensing site  
205 pharmacy will comply with federal and state laws, rules, and  
206 regulations.

207       (b) The procedure for supervising the remote dispensing  
208 site pharmacy and counseling its patients.

209       (c) The procedure for reviewing the prescription drug  
210 inventory and drug records maintained by the remote dispensing  
211 site pharmacy.

212       (d) The policy and procedure for providing appropriate  
213 security to protect the confidentiality and integrity of patient  
214 information.

215       (e) The written plan for recovery from an event that  
216 interrupts or prevents the prescription department manager from  
217 supervising the remote dispensing site pharmacy's operation.

218       (f) The procedure by which the prescription department  
219 manager uses the state prescription drug monitoring program  
220 before authorizing any controlled substance for dispensing.

221       (g) The procedure for maintaining a perpetual inventory of  
222 the controlled substances listed in s. 893.03(2).

223       (h) The specific duties, tasks, and functions that a  
224 registered pharmacy technician is authorized to perform at the  
225 remote dispensing site pharmacy.

226       Section 5. Paragraph (c) of subsection (11) of section  
227 465.022, Florida Statutes, is amended to read:

228       465.022 Pharmacies; general requirements; fees.—

229       (11) A permittee must notify the department of the identity  
230 of the prescription department manager within 10 days after  
231 employment. The prescription department manager must comply with  
232 the following requirements:

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233 (c) A registered pharmacist may not serve as the  
234 prescription department manager in more than one location unless  
235 approved by the board. However, a registered pharmacist may  
236 serve as a prescription department manager for up to two remote  
237 dispensing site pharmacies that are under common control.

238 Section 6. Subsection (1) of section 465.0265, Florida  
239 Statutes, is amended to read:

240 465.0265 Centralized prescription filling.-

241 (1) A pharmacy licensed under this chapter, other than a  
242 remote dispensing site pharmacy permitted under s. 465.0198, may  
243 perform centralized prescription filling for another pharmacy,  
244 provided that the pharmacies have the same owner or have a  
245 written contract specifying the services to be provided by each  
246 pharmacy, the responsibilities of each pharmacy, and the manner  
247 in which the pharmacies will comply with federal and state laws,  
248 rules, and regulations.

249 Section 7. This act shall take effect July 1, 2018.



The Florida Senate

## Committee Agenda Request

**To:** Senator Dana D. Young, Chair  
Committee on Health Policy

**Subject:** Committee Agenda Request

**Date:** December 11, 2017

---

I respectfully request that **Senate Bill #164**, relating to Mammography, and **Senate Bill #848**, relating to Remote Dispensing Site Pharmacies, be placed on the:

- committee agenda at your earliest possible convenience.
- next committee agenda.

A handwritten signature in cursive script that reads "Denise Grimsley".

---

Senator Denise Grimsley  
Florida Senate, District 26

# APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/6/18

Meeting Date

82/8

Bill Number (if applicable)

Topic Telepharmen

Amendment Barcode (if applicable)

Name Audrey Brown

Job Title President + CEO

Address \_\_\_\_\_  
Street

Phone \_\_\_\_\_

City

State

Zip

Email \_\_\_\_\_

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing FL Assoc. of Health Plans

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

THE FLORIDA SENATE  
**APPEARANCE RECORD**

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/6/18  
Meeting Date

SB 848  
Bill Number (if applicable)

Topic Remove Tech Deep

Amendment Barcode (if applicable)

Name Kathy Baldwin

Job Title Florida Society Health System Advocate

Immediate Past President

Address 117 Barton Village Pk

Phone 904-755-2335

Street Jax City FL State 32258 Zip

Email Kathy Baldwin @ bangor.org

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing FSHP

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

**THE FLORIDA SENATE**  
**APPEARANCE RECORD**

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2-6-18  
Meeting Date

SB 40  
Bill Number (if applicable)

Topic \_\_\_\_\_

Amendment Barcode (if applicable)

Name PRENTON McDONALD

Job Title PHARMACEUT

Address 5740 WESTMONT ROAD  
Street

Phone 850-982-9097

MELTON FL 32583  
City State Zip

Email MEPHARM@MCHSI.COM

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing PHARMACEUT

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.



**THE FLORIDA SENATE**  
**APPEARANCE RECORD**

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/6/2018

SB848

*Meeting Date*

*Bill Number (if applicable)*

Topic Remote Dispensing Site Pharmacies

*Amendment Barcode (if applicable)*

Name Michael A. Jackson

Job Title Executive Vice President and CEO

Address 610 North Adams Street

Phone (850) 222-2400

*Street*

Tallahassee

Florida

32301

Email mjackson@pharmview.com

*City*

*State*

*Zip*

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
*(The Chair will read this information into the record.)*

Representing Florida Pharmacy Association

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

*While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.*

***This form is part of the public record for this meeting.***

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/6/2018

Meeting Date

848

Bill Number (if applicable)

Topic Telepharmacy

Amendment Barcode (if applicable)

Name Michael A. Mone

Job Title VP General Counsel - Regulatory

Address 7000 Cardinal Pl

Phone 614-757-5104

Street

Dublin

OH

43017

City

State

Zip

Email michael.mone@cardinalhearth.com

Speaking: [X] For [ ] Against [ ] Information

Waive Speaking: [ ] In Support [ ] Against (The Chair will read this information into the record.)

Representing Cardinal Hearth

Appearing at request of Chair: [ ] Yes [ ] No

Lobbyist registered with Legislature: [ ] Yes [X] No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

THE FLORIDA SENATE  
**APPEARANCE RECORD**

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/6/2018  
Meeting Date

SB 848  
Bill Number (if applicable)

Topic Remote Dispensing Pharmacy

Amendment Barcode (if applicable)

Name James Wright

Job Title pharmacy owner

Address 1108 Lake Dr  
Street

Phone 321-806-3951

Cocoa FL 32922  
City State Zip

Email James.Wright@fivepointsrx.com

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing \_\_\_\_\_

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

# APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/6/2018

Meeting Date

SB 849

Bill Number (if applicable)

Topic Remote Dispensing Site Pharmacies

Amendment Barcode (if applicable)

Name Bill Mincy

Job Title VP PPSC

Address 3375 Capital Circle NE Suite I

Phone 850-553-3595

Street

Tallahassee

FL

32308

City

State

Zip

Email bill.mincy@ppsonline.com

Speaking:  For  Against  Information

PPSC-FPN

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing Small Business Pharmacy Owners

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

**The Florida Senate**  
**BILL ANALYSIS AND FISCAL IMPACT STATEMENT**

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

---

Prepared By: The Professional Staff of the Committee on Health Policy

---

BILL: CS/SB 1494

INTRODUCER: Health Policy Committee, Senator Montford and others

SUBJECT: Prescription Drug Pricing Transparency

DATE: February 6, 2018

REVISED: \_\_\_\_\_

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Lloyd	Stovall	HP	Fav/CS
2.			BI	
3.			AP	

**Please see Section IX. for Additional Information:**

COMMITTEE SUBSTITUTE - Substantial Changes

**I. Summary:**

CS/SB 1494 requires a pharmacist or his or her authorized employee to inform customers of potential lower cost generically equivalent alternatives for their prescriptions and whether a prescription's cost sharing amount exceeds the retail price in the absence of prescription drug coverage. The bill also creates a requirement for pharmacy benefit managers (PBMs) to biennially register with the Office of Insurance Regulation (OIR), provide information on certain key personnel, report within 60 days changes in key personnel and other information, and pay registration and renewal fees that cover administrative costs of the OIR or \$500, whichever is less.

A PBM is a person or entity doing business in this state which contracts to administer or manage prescription drug benefits on behalf of a health insurer or a health maintenance organization (HMO) to residents of this state.

The PBM's contracts with insurers and HMOs must require the PBM to update maximum allowable cost (MAC) information every seven calendar days and include specific terms to prohibit PBMs from limiting a pharmacist's ability to disclose to customers when cost sharing may exceed the retail price of a drug or the availability of a more affordable alternative drug. The bill also prohibits any contract between a PBM and a health insurer or HMO from requiring a customer to pay an amount that exceeds the applicable cost-sharing amount or the retail price of the drug in the absence of prescription drug coverage.

The bill has a small, negative fiscal impact on the Office of Insurance Regulation.

The effective date of the act is July 1, 2018.

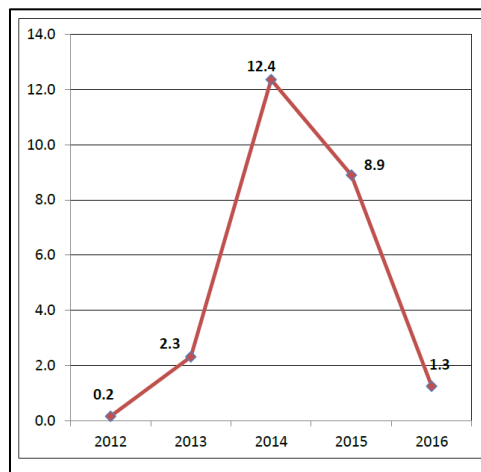
**II. Present Situation:**

**Prescription Drugs Costs**

In 2016, total health care expenditures in the United States reached \$3.3 trillion, a 4.3 percent increase over the 2015 level.<sup>1</sup> Of that amount, prescription drug coverage accounted for \$328.6 billion, up from \$324.5 billion which was only a year to year growth rate of 1.3 percent.<sup>2</sup> In the prior year, 2014 to 2015, the annual growth trend in prescription drugs had been 8.9 percent and then 12.4 percent in the annual period of 2013 to 2014.<sup>3</sup> The large growth rates of these time periods are largely attributed to new medicines for hepatitis C and higher use rates for brand-names medications due to losses in certain patent protections.<sup>4</sup>

The graph below from the Centers for Medicare and Medicaid Services, Office of the Actuary, shows the Annual Growth in Retail Prescription Drug Spending from 2012 through 2016 highlighting the moderate increase in spending from 2015 to 2016 of 1.3.<sup>5</sup> The slowing in 2016 is linked to the approval of fewer new drugs, slower growth in brand name drugs, and a decline in spending in hepatitis C drugs.<sup>6</sup>

*Graph 1 - Annual Growth in Retail Prescription Drug Spending - 2012 - 2016*



SOURCE: Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics

As shown in the Table 1., the largest payer for prescription drugs is private health insurance coverage at 43 percent.<sup>7</sup>

<sup>1</sup> Micah Hartman, Anne B. Martin, Nathan Espinosa, et al, *National Health Care Spending in 2016: Spending and Enrollment Growth Slow After Initial Coverage Expansions*, Health Affairs – January 2018 (December 6, 2017), p. 152, available at <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2017.1299> (last visited Feb. 1, 2018).

<sup>2</sup> *Id* at 153.

<sup>3</sup> *Id*.

<sup>4</sup> *Id* at 155.

<sup>5</sup> Centers for Medicare and Medicaid Services, Office of the Actuary, National Health Statistics Group, *Annual Growth in Retail Prescription Drug Spending, 2012-2016*, Slide 12, available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/NHE-Presentation-Slides.pdf> (last visited Feb. 1, 2018).

<sup>6</sup> *Id*.

<sup>7</sup> *Supra* note 5, at 155.

Utilization data shows an increase in 2016 in the number of prescriptions dispensed, especially for drugs that treat high blood pressure, high cholesterol, and mental health.<sup>8</sup> An increase in the use of specialty drugs may have also played a part in the increased costs. Expenditures on specialty drugs are rising more rapidly than on other drugs; however, there is no clear definition of what is a “specialty drug.”

Payer	Percentage of Market	Percent Growth	
		2015	2016
Overall – All Payers	100%	8.9%	1.3%
Private Health Insurance	43%	10.4	0.8
Medicare	29%	9.3	2.8
Medicaid	10%	13.4	5.5
Out-of-pocket spending	14%	1.6	(1.0)

A different review of national prescription drug data from 2010 to 2014 attributes the rise in prescription drug spending to multiple factors from 2010 to 2014: population growth (10 percent), an increase in the number of prescriptions dispensed per person (30 percent), economy-wide inflation (30 percent), and the remaining 30 percent to changes in the composition of drugs prescribed toward higher priced products or price increases for drugs which drove average price increases in excess of general inflation.<sup>11</sup>

### **Pharmacy Benefits Managers (PBMs)**

Health insurers, HMOs, and other purchasers of health benefits coverage increasingly utilize PBMs to provide a range of services related to the acquisition and management of prescription drugs.

The PBMs negotiate with retail pharmacies to obtain various discounts on prescription drug prices. PBMs also provide the following services to its customers:

- Pharmacy claims processing;
- Mail-order pharmacy services;
- Rebate negotiations with drug manufacturers;
- Development of pharmacy networks;
- Formulary management;<sup>12</sup>
- Prospective and retrospective drug utilization reviews;
- Offer incentives to plan participations to use generic drug substitutions; and
- Disease management programs.

<sup>8</sup> *Supra* note 1, at 156.

<sup>9</sup> *Id.*

<sup>10</sup> Centers for Medicare and Medicaid Services, National Health Expenditure Data – Historical, 2016 - Table 16 – Retail Prescription Expenditures (Average Annual Percent Change from Previous Year Shown) (last modified Jan. 8, 2018) available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html> (last visited Feb. 1, 2018).

<sup>11</sup> *Supra* note 6, at 5.

<sup>12</sup> A list of drugs that a health plan uses to make reimbursement decisions.

The decision of plan sponsors to use PBMs to control pharmacy benefit costs, however, can shift business away from retail pharmacies. A PBM can often use aggregate volume to offer its clients savings with discounts from drugmakers and drugstores.<sup>13</sup> An estimated 266 million Americans have their pharmacy benefits managed by a PBM.<sup>14</sup> An industry advocacy group estimates that PBMs have saved an average of \$941 per person per year compared to unmanaged expenditures,<sup>15</sup> including a total of \$43.4 billion across all payors in Florida.<sup>16</sup>

Approximately 60 PBMs are operational nationally, and the three largest – Express Scripts, CVS/Caremark, and OptumRx – report filling or managing a combined 5.1 billion prescriptions annually.<sup>17,18,19</sup> PBMs use different tools and methods to reduce costs and find savings for payors through reductions in the unit costs of drugs, the mix of drugs that are prescribed, and in the modification of patient behavior through either reduction of inappropriate use of certain prescriptions or improvements in patient adherence to drug regimens.<sup>20</sup>

Examples of unit cost reductions may be in discounts to pharmacy network participants, use of manufacturer rebates, or the increased use of mail order pharmacies. PBMs may also encourage a greater use of generic drugs over certain brand name drugs, require step therapy, or implement tiered copayment levels for different types of prescriptions to achieve desired savings. Reducing or eliminating certain types of patient behaviors through quantity limits, prior authorization requirements, or other patient management programs are also tools that may be used.<sup>21</sup> Each PBM may generate savings from these actions which may also translate into savings for the patient and the payor.

Most patients assume that their share of cost of that prescription will be less than the actual retail cost of the prescription (or the non-insured cash price) of the drug. However, this may not always be the case. In cases where the retail price of the drug is less than a patient's applicable cost share, a patient could pay the regular cost sharing, regardless of the retail price; pay the lower retail price; or, some other amount based on the contract terms between the PBM and the pharmacy. If a pharmacist is obligated to charge this higher price, the PBM may collect as revenue the difference between a patient's cost share and the lower retail price.<sup>22</sup> One recent *New York Times* article cited a statistic that for up to 10 percent of drug transactions, the patient could

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<sup>13</sup> Bill Alpert, *Pharmacy Benefit Managers Under Pressure*, Barrons (July 23, 2016) available at <https://www.barrons.com/articles/pharmacy-benefit-managers-under-fire-1469247082> (last visited Feb. 1, 2018).

<sup>14</sup> Visante, Prepared for the Pharmaceutical Care Management Association, *The Return on Investment on PBM Services* (November 2016), Slide 2, available at <https://www.pcmantet.org/wp-content/uploads/2016/11/ROI-on-PBM-Services-FINAL.pdf> (last visited Feb. 1, 2018).

<sup>15</sup> *Id.*

<sup>16</sup> Pharmaceutical Care Management Association, *How Much PBMs are Saving: State by State* <http://drugbenefitsolutions.com/prescription-costs/> (last visited Feb. 1, 2018).

<sup>17</sup> Express Scripts, *Corporate Overview* <https://lab.express-scripts.com/about/> (last visited Feb. 1, 2018).

<sup>18</sup> CVS Health, *Investor Fact Sheet* (November 2017) available at <http://investors.cvshealth.com/~media/Files/C/CVS-IR-v3/documents/cvs-factsheet-111017.pdf> (last visited Feb. 1, 2018).

<sup>19</sup> OptumRx, *About Optum* <https://www.optum.com/about.html> (last visited Feb. 1, 2018).

<sup>20</sup> *Supra* note 15, at 4.

<sup>21</sup> *Id.*

<sup>22</sup> National Community Pharmacists Association. *Statement for the Record: National Community Pharmacists Association*, U.S. House Committee on Oversight and Government Reform, (Feb. 4, 2016), available at <http://www.ncpa.co/pdf/ncpa-ogr-statement.pdf> (last visited Feb. 1, 2018).



have gotten a better price without an insurance card for a prescription than with his or her coverage.<sup>23</sup>

### **Maximum Allowable Cost Pricing List**

Contracts between a PBM and health plan sponsors specify how much the health sponsors will pay the PBMs for brand name and generic drugs. These prices are typically set as a discount off the average wholesale price<sup>24</sup> for brand-name drugs and at a maximum allowable cost (MAC)<sup>25</sup> for generic drugs, plus a dispensing fee. The MAC represents the upper limit price that a payor, such as a state or a plan sponsor has through its PBM, will pay or reimburse for generic and brand drugs that have generic versions available.<sup>26</sup> A national survey represents that 92 percent of large employers have such a list in place through their PBM.<sup>27</sup>

A MAC pricing list creates a standard reimbursement amount for identical products, and is a common cost management tool developed from a proprietary survey of wholesale prices in the marketplace, taking into account market share, inventory, reasonable profits margins, and other factors. The purpose of the MAC pricing list is to ensure that the pharmacy is motivated to seek and purchase generic drugs at the lowest price in the marketplace.

The federal Medicare Part D program and 44 state Medicaid programs use some type of MAC price lists to reduce costs.<sup>28</sup>

### **Regulation of Pharmacies and Pharmacy Benefit Management Companies**

In Florida, PBMs are not regulated or licensed. However, the Board of Pharmacy under ch. 465, F.S., regulates pharmacies, adopts rules to implement the provisions of the Pharmacy Act, and takes other actions according to duties conferred upon it.<sup>29</sup> Each pharmacy is subject to inspection by the Department of Health (DOH) and may be disciplined for violations of applicable laws and rules relating to a pharmacy.<sup>30</sup>

A PBM administers the prescription drug part of a health plan on behalf of the plan sponsor, self-insured employers, insurers, and health maintenance organizations. Some states require PBMs to

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<sup>23</sup> Charles OrNSTein, *When Buying Prescription Drugs, Some Pay More With Insurance Than Without It*, The New York Times, (December 9, 2017), available at <https://www.nytimes.com/2017/12/09/health/drug-prices-generics-insurance.html> (last visited Feb. 1, 2018).

<sup>24</sup> Average wholesale price is the retail list price (sticker price) or the average price that manufacturers recommend wholesalers sell to physicians, pharmacies, and others, such as hospitals.

<sup>25</sup> Maximum allowable cost is a price set for generic drugs and is the maximum amount that the plan sponsor will pay for a specific drug.

<sup>26</sup> Brent J. Eberle, RPh, Alan Van Amber, *Your PBM's MAC List Impacts Your Bottom Line*, Managed Healthcare Executive, (December 1, 2008), available at <http://managedhealthcareexecutive.modernmedicine.com/managed-healthcare-executive/content/your-pbms-mac-list-impacts-your-bottom-line> (last visited Feb. 2, 2018).

<sup>27</sup> *Id.*

<sup>28</sup> Medicaid.gov, *Medicaid Covered Outpatient Prescription Drug Reimbursement Information by State (Quarter Ending September 2017)*, available at <https://www.medicaid.gov/medicaid/prescription-drugs/state-prescription-drug-resources/drug-reimbursement-information/index.html> (last visited Feb. 1, 2018).

<sup>29</sup> Sections 465.005 and 465.022, F.S.

<sup>30</sup> Sections 465.015 and 465.016, F.S.

either register with state insurance regulators or be licensed as third-party administrators.<sup>31</sup> States enacting regulations of PBMs are as follows.<sup>32</sup>

Licensure/Registration of PBMs		Patient Protections and Pricing Transparency	Both Licensure and Patient Protections
Iowa (2007) Kansas (2006) Kentucky (2016) Maryland (2003) New Mexico (2016)	North Dakota (2005) Rhode Island (2004) South Dakota (2004) Wyoming (2016)	Georgia (2017) Louisiana (2016) North Carolina (2017) Tennessee (2009) Texas (2017)	Arkansas (2015) Connecticut (2007, 2017) Washington (2014)

A PBM may obtain accreditation from various accrediting bodies that determine if certain national standards are met. Accreditation is an evaluative, rigorous, transparent, and comprehensive process in which a health care organization undergoes an examination of its systems, processes, and performance by an accrediting body to ensure that it is conducting business in a manner that meets predetermined criteria and is consistent with national standards.

At each contract execution or renewal between a PBM and a pharmacy, current law requires the contract to include requirements that the MAC pricing will be updated at least every seven calendar days and that a process will be maintained to eliminate drugs in a timely manner from the MAC lists or drug price lists and to remain consistent with changes in pricing data that is used in formulating the MAC prices and product availability.<sup>33</sup>

**III. Effect of Proposed Changes:**

**Section 1** amends s. 465.0244, F.S., to require a pharmacist or his or her authorized employee to notify customers:

- If a less expensive, generically equivalent drug product is available for his or her prescription; and
- If the customer’s cost sharing obligation for his or her prescription exceeds the retail price of the customer’s prescription in the absence of prescription drug coverage.

**Section 2** repeals s. 465.1862, F.S., relating to pharmacy benefit manager contracts. The provisions are moved to newly created sections specific to different types of products under the insurance code which fall under the jurisdiction of the OIR.

**Section 3** creates s. 624.490, F.S., to implement a PBM registration and bi-annual renewal process within the OIR.

<sup>31</sup> Joanne Wojcik, *States Try to Regulate Pharmacy Benefit Managers*, Business Insurance (August 22, 2010), available at <http://www.businessinsurance.com/article/20100822/ISSUE07/308229997> (last visited Feb. 1, 2018).

<sup>32</sup> See also Pharmacists United for Truth and Transparency, *State Regulations in Pharmacy Benefit Management*, available at [https://www.marleydrug.com/wp-content/uploads/2016/05/PUTT\\_State-Regulations\\_061713a.pdf](https://www.marleydrug.com/wp-content/uploads/2016/05/PUTT_State-Regulations_061713a.pdf) (last viewed Feb. 1, 2018), and National Association of Community Pharmacists, *State Laws Reforming the Practices of Pharmacy Benefit Managers (PBMs)*, available at [http://www.ncpanet.org/pdf/leg/nov12/pbm\\_enacted\\_legislation.pdf](http://www.ncpanet.org/pdf/leg/nov12/pbm_enacted_legislation.pdf) (last viewed Feb. 1, 2018).

<sup>33</sup> Section 465.1862(2), F.S.

The bill also defines a pharmacy benefit manager to mean a person or entity who is doing business in this state which contracts to administer prescription drug benefits on behalf of a health insurer or a health maintenance organization to residents of this state.

To register, the PBM is required to submit:

- A registration fee;
- A copy of the PBM's corporate charter, articles of incorporation, or other charter document;
- A completed registration form showing the identity, address, and taxpayer identification number, as applicable, of:
  - The registrant;
  - The chief executive officer;
  - The chief financial officer; and
  - Each person or entity responsible for the day-to-day operations and affairs of the registrant, or the similarly situated individuals for each of those positions.

Upon receipt of a completed registration form and the registration fee, the OIR is to issue a registration certification to the PBM. The registration certificate is valid for two years from the date issued. The certificate is nontransferable.

The bill directs the OIR to set the registration and renewal fees in an amount sufficient to cover the costs of administering the registration process or \$500, whichever is less.

The PBM must report any changes to the OIR in the controlling interests of the PBM within 60 days of the change.

The OIR is directed to adopt rules to administer the registration process.

**Sections 4, 5 and 6** create ss. 627.64741, 627.6572, and 641.314, F.S., to require a contract between a PBM and a health insurer that issues individual policies, large group health insurance policies, or HMO and a PBM to include certain specific terms:

- The PBM must update its MAC information at least every seven calendar days. The term "MAC" is defined as the per unit amount that a PBM reimburses a pharmacist for a prescription drug, excluding dispensing fees.
- The PBM must maintain a process that will, in a timely manner, eliminate drugs from the MAC lists or modify drug prices to remain consistent with changes in pricing data used in formulating MAC and product availability.
- The PBM is prohibited from limiting a pharmacist's ability to disclose to the consumer whether the consumer's cost sharing obligation exceeds the retail price for a covered prescription drug and disclosure of the availability of a more affordable alternative drug.

The PBM is prohibited from requiring a consumer to pay for a prescription in an amount which exceeds the lesser of the applicable cost sharing amount or the retail price in the absence of prescription drug coverage.

The changes in this act are effective for contracts entered into or renewed on or after July 1, 2018.

**Section 6** provides an effective date for the act of July 1, 2018.

**IV. Constitutional Issues:****A. Municipality/County Mandates Restrictions:**

None.

**B. Public Records/Open Meetings Issues:**

None.

**C. Trust Funds Restrictions:**

None.

**V. Fiscal Impact Statement:****A. Tax/Fee Issues:**

None.

**B. Private Sector Impact:**

Each pharmacy benefit manager seeking to do business in the state will be required to complete a new registration process with the OIR and pay a registration fee, the amount of which is to be determined by the OIR. The PBM will incur administrative costs and time to complete the registration process and to maintain updated information with the OIR.

CS/SB 1494 prohibits a PBM from limiting a pharmacist from notifying a patient if the patient's cost sharing obligation exceeds the retail price for a covered drug and of the availability of a more affordable alternative drug. The ability of the pharmacist to notify the patient of the availability of alternative drugs may, according to some insurers, increase the costs of health care.

**C. Government Sector Impact:**

The OIR will be required to implement and manage a registration process for PBMs under the bill. The initial and biennial registration certificate fees would be determined by the OIR and could not exceed the costs of administering the process or \$500, whichever is less.

The OIR's fiscal impact statement includes a request for an additional Analyst to work the PBM registrations/renewal and updates to registrations received throughout the year. Costs to upgrade technology for the new PBM registration process are also shown in the chart below.

Office of Insurance Regulation – Fiscal Impact Statement <sup>34</sup>		
Item	Description	Total
<u>Salary and Benefits</u>		\$74,141
Reinsurance/Financial Specialist (1 FTE)	Work initial registration filings from PBMs and continued administration of registrants due to changes in controlling interests and monitoring/documenting renewals of registrations expiring at the end of two years from the date of issuance.	
<u>Contracted Services</u> Technology System Upgrade (one time)	Update technology systems and operations to create registration process for PBMs.	\$5,000
<b>FIRST YEAR ANNUAL TOTAL:</b>		<b>\$79,141</b>

**VI. Technical Deficiencies:**

The bill requires the PBM to submit articles of incorporation or other charter documents to register with the OIR. However, the bill also specifies that the OIR shall issue a registration certificate upon receipt of a completed registration form and registration fee and does not require submission of the articles of incorporation before the certificate is issued. The current order of approval could result in the OIR issuing a PBM certificate to a PBM that is not in compliance with the Florida Statutes.<sup>35</sup>

**VII. Related Issues:**

The OIR noted that the bill does not include any guidelines by which the OIR could evaluate, approve, or disapprove the registration application or renewal of a PBM other than the completeness of a form.<sup>36</sup> This may result in the approval of an individual with a criminal background, for example. Additionally, the bill requires the collection of taxpayer identification numbers, but does not authorize the OIR to conduct background screenings. The OIR requests that this information be removed from the registration form unless the office can use the data to conduct screenings.

With an effective date of July 1, 2018, the bill may have an impact on the insurance and HMO rates already set and filed for 2018, according to the OIR.<sup>37</sup> It was suggested by the OIR that it may be more appropriate to modify the effective date to January 1, 2019, to coincide with the effective date of the insurer and HMO rate cycles.<sup>38</sup>

Finally, the OIR requested the authority to conduct market examinations on the registered PBMs and to require the PBMs to pay for the costs of those exams under s. 624.3161, F.S., as is done for all other market conduct examinations.

<sup>34</sup> Office of Insurance Regulation, *Senate Bill 1494 Analysis* (January 15, 2018), p. 4 (on file with the Senate Committee on Health Policy).

<sup>35</sup> *Id.*

<sup>36</sup> *Id.*

<sup>37</sup> *Id.*

<sup>38</sup> *Id.*

**VIII. Statutes Affected:**

This bill substantially amends section 465.0244 of the Florida Statutes.

This bill creates the following sections of the Florida Statutes: 624.490, 627.64741, 627.6572, and 641.314.

This bill repeals section 465.1862 of the Florida Statutes.

**IX. Additional Information:**

**A. Committee Substitute – Statement of Substantial Changes:**  
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

**CS by Health Policy on February 6, 2018:**

The CS adds the ability for a pharmacist's authorized employee, in addition to the requirement for a pharmacist, to inform a customer of the availability of less expensive, generically equivalent drug product for his or her prescription and as to whether a customer's cost-sharing obligation exceeds the retail price of the prescription drug in the absence of prescription drug coverage.

The CS repeals s. 465.1862, F.S., relating to pharmacy benefits manager contracts; however, these provisions are moved to the insurance code under the jurisdiction of the OIR.

Additionally, the CS modifies the PBM registration process by:

- Eliminating requirements for an individual's social security number;
- Removing the requirement that PBM's submit the names of those individuals or entities with 10 percent or greater controlling ownership interest with the registration or biennial renewal;
- Deleting the definition of controlling interest;
- Extending the notice period for information changes to 60 days from 30 days; and
- Capping the maximum fees that may be charged by the OIR for administering the process at \$500.

The CS deletes the requirement that the contracts between PBMs and insurers and HMOs include a prohibition against limiting the pharmacy's or PBM's ability to substitute a less expensive, generically equivalent drug product for a brand name drug.

For contracts between health insurers and HMOs and the PBMs, the CS amends the comparison points relating to the consumer's out of pocket cost for prescription drugs from three to two, so the consumer pays the lesser of the applicable cost-sharing amount or the retail price of the drug in the absence of prescription drug coverage. The third reference point, the allowable claim amount for the prescription drug, is deleted.

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The CS also creates s. 627.6572, F.S, making the provisions relating to PBM contract reporting on MAC cost information and contract provision requirements applicable to group health insurance policies.

**B. Amendments:**

None.

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This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.

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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
02/06/2018	.	
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The Committee on Health Policy (Montford) recommended the following:

**Senate Amendment (with title amendment)**

Delete everything after the enacting clause  
and insert:

Section 1. Section 465.0244, Florida Statutes, is amended  
to read:

465.0244 Information disclosure.—

(1) Every pharmacy shall make available on its website a  
hyperlink to the health information that is disseminated by the  
Agency for Health Care Administration pursuant to s. 408.05(3)





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11 and shall place in the area where customers receive filled  
12 prescriptions notice that such information is available  
13 electronically and the address of its Internet website.

14 (2) In addition to the requirements of s. 465.025, a  
15 pharmacist or her or his authorized employee must inform a  
16 customer of a less expensive, generically equivalent drug  
17 product for her or his prescription and as to whether the  
18 customer's cost-sharing obligation exceeds the retail price of  
19 the prescription in the absence of prescription drug coverage.

20 Section 2. Section 465.1862, Florida Statutes, is repealed.

21 Section 3. Section 624.490, Florida Statutes, is created to  
22 read:

23 624.490 Registration of pharmacy benefit managers.—

24 (1) As used in this section, the term "pharmacy benefit  
25 manager" means a person or entity doing business in this state  
26 which contracts to administer prescription drug benefits on  
27 behalf of a health insurer or a health maintenance organization  
28 to residents of this state.

29 (2) To conduct business in this state, a pharmacy benefit  
30 manager must register with the office. To register, a pharmacy  
31 benefit manager shall submit:

32 (a) A fee determined by the office.

33 (b) A copy of the registrant's corporate charter, articles  
34 of incorporation, or other charter document.

35 (c) A form established by the office containing the  
36 identity, address, and taxpayer identification number, when  
37 applicable, of:

38 1. The registrant.

39 2. The chief executive officer or a similarly titled person



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40 responsible for the executive oversight of the registrant.

41 3. The chief financial officer or a similarly titled person  
42 responsible for the financial oversight of the registrant.

43 4. Each person or entity responsible for the affairs of the  
44 registrant, including, but not limited to, the day-to-day  
45 operations of the registrant.

46 (3) The registrant shall report any change in information  
47 required by subsection (2) to the office in writing within 60  
48 days after the change occurs.

49 (4) Upon receipt of a completed registration form and the  
50 registration fee, the office shall issue a registration  
51 certificate. The certificate may be in paper or electronic form,  
52 and shall clearly indicate the expiration date of the  
53 registration. Registration certificates are nontransferable.

54 (5) A registration certificate is valid for 2 years from  
55 its date of issue. The office shall set an initial registration  
56 fee and a registration renewal fee, both of which shall be  
57 nonrefundable. Total fees may not exceed the cost of  
58 administering this section or \$500, whichever is less.

59 (6) The office shall adopt rules necessary to implement  
60 this section.

61 Section 4. Section 627.64741, Florida Statutes, is created  
62 to read:

63 627.64741 Pharmacy benefit manager contracts.—

64 (1) As used in this section, the term:

65 (a) "Maximum allowable cost" means the per-unit amount that  
66 a pharmacy benefit manager reimburses a pharmacist for a  
67 prescription drug, excluding dispensing fees, prior to the  
68 application of copayments, coinsurance, and other cost-sharing



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69 charges, if any.

70 (b) "Pharmacy benefit manager" means a person or entity  
71 doing business in this state which contracts to administer or  
72 manage prescription drug benefits on behalf of a health insurer  
73 to residents of this state.

74 (2) A contract between a health insurer and a pharmacy  
75 benefit manager must require that the pharmacy benefit manager:

76 (a) Update maximum allowable cost pricing information at  
77 least every 7 calendar days.

78 (b) Maintain a process that will, in a timely manner,  
79 eliminate drugs from maximum allowable cost lists or modify drug  
80 prices to remain consistent with changes in pricing data used in  
81 formulating maximum allowable cost prices and product  
82 availability.

83 (3) A contract between a health insurer and a pharmacy  
84 benefit manager must prohibit the pharmacy benefit manager from  
85 limiting a pharmacist's ability to disclose whether the cost-  
86 sharing obligation exceeds the retail price for a covered  
87 prescription drug, and the availability of a more affordable  
88 alternative drug, pursuant to s. 465.0244.

89 (4) A contract between a health insurer and a pharmacy  
90 benefit manager must prohibit the pharmacy benefit manager from  
91 requiring an insured to make a payment for a prescription drug  
92 at the point of sale in an amount that exceeds the lesser of:

93 (a) The applicable cost-sharing amount; or

94 (b) The retail price of the drug in the absence of  
95 prescription drug coverage.

96 (5) This section applies to contracts entered into or  
97 renewed on or after July 1, 2018.



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98 Section 5. Section 627.6572, Florida Statutes, is created  
99 to read:

100 627.6572 Pharmacy benefit manager contracts.—

101 (1) As used in this section, the term:

102 (a) "Maximum allowable cost" means the per-unit amount that  
103 a pharmacy benefit manager reimburses a pharmacist for a  
104 prescription drug, excluding dispensing fees, prior to the  
105 application of copayments, coinsurance, and any other cost-  
106 sharing charges.

107 (b) "Pharmacy benefit manager" means a person or entity  
108 doing business in this state which contracts to administer or  
109 manage prescription drug benefits on behalf of a health insurer  
110 to residents of this state.

111 (2) A contract between a health insurer and a pharmacy  
112 benefit manager must require that the pharmacy benefit manager:

113 (a) Update maximum allowable cost pricing information at  
114 least every 7 calendar days.

115 (b) Maintain a process that will, in a timely manner,  
116 eliminate drugs from maximum allowable cost lists or modify drug  
117 prices to remain consistent with changes in pricing data used in  
118 formulating maximum allowable cost prices and product  
119 availability.

120 (3) A contract between a health insurer and a pharmacy  
121 benefit manager must prohibit the pharmacy benefit manager from  
122 limiting a pharmacist's ability to disclose whether the cost-  
123 sharing obligation exceeds the retail price for a covered  
124 prescription drug, and the availability of a more affordable  
125 alternative drug, pursuant to s. 465.0244.

126 (4) A contract between a health insurer and a pharmacy



127 benefit manager must prohibit the pharmacy benefit manager from  
128 requiring an insured to make a payment for a prescription drug  
129 at the point of sale in an amount that exceeds the lesser of:

- 130 (a) The applicable cost-sharing amount; or  
131 (b) The retail price of the drug in the absence of  
132 prescription drug coverage.

133 (5) This section applies to contracts entered into or  
134 renewed on or after July 1, 2018.

135 Section 6. Section 641.314, Florida Statutes, is created to  
136 read:

137 641.314 Pharmacy benefit manager contracts.-

138 (1) As used in this section, the term:

139 (a) "Maximum allowable cost" means the per-unit amount that  
140 a pharmacy benefit manager reimburses a pharmacist for a  
141 prescription drug, excluding dispensing fees, prior to the  
142 application of copayments, coinsurance, and any other cost-  
143 sharing charges.

144 (b) "Pharmacy benefit manager" means a person or entity  
145 doing business in this state which contracts to administer or  
146 manage prescription drug benefits on behalf of a health  
147 maintenance organization to residents of this state.

148 (2) A contract between a health maintenance organization  
149 and a pharmacy benefit manager must require that the pharmacy  
150 benefit manager:

151 (a) Update maximum allowable cost pricing information at  
152 least every 7 calendar days.

153 (b) Maintain a process that will, in a timely manner,  
154 eliminate drugs from maximum allowable cost lists or modify drug  
155 prices to remain consistent with changes in pricing data used in



156 formulating maximum allowable cost prices and product  
157 availability.

158 (3) A contract between a health maintenance organization  
159 and a pharmacy benefit manager must prohibit the pharmacy  
160 benefit manager from limiting a pharmacist's ability to disclose  
161 whether the cost-sharing obligation exceeds the retail price for  
162 a covered prescription drug, and the availability of a more  
163 affordable alternative drug, pursuant to s. 465.0244.

164 (4) A contract between a health maintenance organization  
165 and a pharmacy benefit manager must prohibit the pharmacy  
166 benefit manager from requiring a subscriber to make a payment  
167 for a prescription drug at the point of sale in an amount that  
168 exceeds the lesser of:

169 (a) The applicable cost-sharing amount; or

170 (b) The retail price of the drug in the absence of  
171 prescription drug coverage or programs that reduce the cost of a  
172 drug to the patient.

173 (5) This section applies to contracts entered into or  
174 renewed on or after July 1, 2018.

175 Section 7. This act shall take effect July 1, 2018.

177 ===== T I T L E A M E N D M E N T =====

178 And the title is amended as follows:

179 Delete everything before the enacting clause  
180 and insert:

181 A bill to be entitled

182 An act relating to prescription drug pricing  
183 transparency; amending s. 465.0244, F.S.; requiring  
184 pharmacists to inform customers of less expensive,



167480

185 generically equivalent drugs for their prescriptions  
186 and as to whether customers' cost-sharing obligations  
187 exceed the retail price of their prescriptions;  
188 repealing s. 465.1862, F.S., relating to pharmacy  
189 benefit manager contracts; creating s. 624.490, F.S.;  
190 defining the term "pharmacy benefit manager";  
191 requiring a pharmacy benefit manager to register with  
192 the Office of Insurance Regulation; providing  
193 requirements and terms of registration, including the  
194 payment of a registration fee; requiring the office to  
195 issue certificates of registration and to set an  
196 initial registration fee and a renewal fee, which may  
197 not exceed a specified amount; requiring the office to  
198 adopt rules; creating ss. 627.64741, 627.6572, and  
199 641.314, F.S.; defining the terms "maximum allowable  
200 cost" and "pharmacy benefit manager"; requiring that  
201 certain terms be included in a contract between a  
202 health insurer or a health maintenance organization  
203 and a pharmacy benefit manager; providing  
204 applicability; providing an effective date.



542312

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
02/06/2018	.	
	.	
	.	
	.	

---

The Committee on Health Policy (Hutson) recommended the following:

- 1       **Senate Amendment to Amendment (167480)**
- 2
- 3       Delete lines 171 - 172
- 4       and insert:
- 5       prescription drug coverage.



By Senator Montford

3-00778D-18

20181494\_\_

1                   A bill to be entitled  
2       An act relating to prescription drug pricing  
3       transparency; amending s. 465.0244, F.S.; requiring a  
4       pharmacist to inform a customer of a lower cost  
5       alternative to a prescription and of whether the  
6       customer's cost-sharing obligation exceeds the retail  
7       price of the prescription; creating s. 624.49, F.S.;  
8       defining the term "pharmacy benefit manager";  
9       requiring a pharmacy benefit manager to register with  
10      the Office of Insurance Regulation; providing  
11      requirements and terms of registration, including the  
12      payment of a registration fee; requiring the office to  
13      issue certificates of registration and to set an  
14      initial registration fee and a renewal fee; requiring  
15      the office to adopt rules; creating ss. 627.64741 and  
16      641.314, F.S.; defining the terms "maximum allowable  
17      cost" and "pharmacy benefit manager"; requiring that  
18      certain terms be included in a contract between a  
19      health insurer or a health maintenance organization  
20      and a pharmacy benefit manager, respectively;  
21      providing applicability; providing an effective date.

22  
23 Be It Enacted by the Legislature of the State of Florida:

24  
25       Section 1. Section 465.0244, Florida Statutes, is amended  
26 to read:

27       465.0244 Information disclosure.—

28       (1) Every pharmacy shall make available on its website a  
29 hyperlink to the health information that is disseminated by the

3-00778D-18

20181494

30 Agency for Health Care Administration pursuant to s. 408.05(3)  
31 and shall place in the area where customers receive filled  
32 prescriptions a notice that such information is available  
33 electronically and the address of its ~~Internet~~ website.

34 (2) In addition to the requirements of s. 465.025, a  
35 pharmacist must inform a customer of a lower cost alternative  
36 for his or her prescription and of whether the customer's cost-  
37 sharing obligation exceeds the retail price of the prescription  
38 in the absence of prescription drug coverage.

39 Section 2. Section 624.49, Florida Statutes, is created to  
40 read:

41 624.49 Registration of pharmacy benefit managers.—

42 (1) As used in this section, "pharmacy benefit manager"  
43 means a person or entity doing business in this state which  
44 contracts to administer prescription drug benefits on behalf of  
45 a health insurer or a health maintenance organization.

46 (2) To conduct business in this state, a pharmacy benefit  
47 manager must register with the Office of Insurance Regulation.  
48 To register, a pharmacy benefit manager must submit a fee  
49 determined by the office, a copy of the registrant's corporate  
50 charter, articles of incorporation, or other charter document,  
51 and a form established by the office containing the identity,  
52 address, and either the social security number or taxpayer  
53 identification number of all of the following persons:

54 (a) The registrant;

55 (b) The chief executive officer or a similarly titled  
56 person responsible for the executive oversight of the  
57 registrant;

58 (c) The chief financial officer or a similarly titled

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59 person responsible for the financial oversight of the  
60 registrant; and

61 (d) Each controlling interest of the registrant. For the  
62 purpose of this section, "controlling interest" means a person  
63 or entity that serves as an officer of, is on the board of  
64 directors of, or has a 10 percent or greater ownership interest  
65 in the registrant.

66 (3) The registrant shall report a change in any controlling  
67 interest of the registrant to the office in writing within 30  
68 days after the change.

69 (4) Upon receipt of a complete registration form and the  
70 registration fee, the office shall issue a registration  
71 certificate. The certificate may be in paper or electronic form,  
72 and must clearly indicate the expiration date of the  
73 registration. Registration certificates are nontransferable.

74 (5) (a) The term of registration shall be 2 years from the  
75 date of issuance.

76 (b) The office shall set an initial registration fee and a  
77 renewal fee, which are nonrefundable. Total fees may not exceed  
78 the cost of administering this section.

79 (6) The office shall adopt rules necessary to administer  
80 this section.

81 Section 3. Section 627.64741, Florida Statutes, is created  
82 to read:

83 627.64741 Pharmacy benefit manager contracts.—

84 (1) As used in this section, the term:

85 (a) "Maximum allowable cost" means the per-unit amount that  
86 a pharmacy benefit manager may reimburse a pharmacist for a  
87 prescription drug, excluding dispensing fees, before the

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88 application of copayments, coinsurance, or any other cost-  
89 sharing charges.

90 (b) "Pharmacy benefit manager" means a person or entity  
91 doing business in this state which contracts to administer or  
92 manage prescription drug benefits on behalf of a health insurer  
93 to residents of this state.

94 (2) A contract between a health insurer and a pharmacy  
95 benefit manager must include requirements that the pharmacy  
96 benefit manager:

97 (a) Update maximum allowable cost information at least  
98 every 7 calendar days; and

99 (b) Maintain a process that will, in a timely manner,  
100 eliminate drugs from maximum allowable cost lists or modify drug  
101 prices to remain consistent with changes in pricing data used in  
102 formulating maximum allowable costs and product availability.

103 (3) A contract between a health insurer and a pharmacy  
104 benefit manager must prohibit the pharmacy benefit manager from  
105 limiting a pharmacy's or pharmacist's ability to substitute a  
106 less expensive, generically equivalent drug product for a brand  
107 name drug, pursuant to s. 465.025, or to disclose to a  
108 subscriber whether the subscriber's cost-sharing obligation  
109 exceeds the retail price for a covered prescription drug, and  
110 the availability of a more affordable alternative drug, pursuant  
111 to s. 465.0244.

112 (4) A contract between a health insurer and a pharmacy  
113 benefit manager must prohibit the pharmacy benefit manager from  
114 requiring a subscriber to pay for a prescription drug at the  
115 point of sale in an amount greater than the lesser of:

116 (a) The applicable cost-sharing amount;

3-00778D-18

20181494\_\_

117 (b) The allowable claim amount for the prescription drug;  
118 and

119 (c) The retail price of the drug in the absence of  
120 prescription drug coverage or programs that otherwise reduce the  
121 cost of a drug to the patient.

122 (5) This section applies to contracts entered into or  
123 renewed on or after July 1, 2018.

124 Section 4. Section 641.314, Florida Statutes, is created to  
125 read:

126 641.314 Pharmacy benefit manager contracts.—

127 (1) As used in this section, the term:

128 (a) "Maximum allowable cost" means the per-unit amount that  
129 a pharmacy benefit manager reimburses a pharmacist for a  
130 prescription drug, excluding dispensing fees, before the  
131 application of copayments, coinsurance, or any other cost-  
132 sharing charges.

133 (b) "Pharmacy benefit manager" means a person or entity  
134 doing business in this state which contracts to administer or  
135 manage prescription drug benefits on behalf of a health  
136 maintenance organization to residents of this state.

137 (2) A contract between a health maintenance organization  
138 and a pharmacy benefit manager must include requirements that  
139 the pharmacy benefit manager:

140 (a) Update maximum allowable cost information at least  
141 every 7 calendar days; and

142 (b) Maintain a process that will, in a timely manner,  
143 eliminate drugs from maximum allowable cost lists or modify drug  
144 prices to remain consistent with changes in pricing data used in  
145 formulating maximum allowable costs and product availability.

3-00778D-18

20181494\_\_

146       (3) A contract between a health maintenance organization  
147 and a pharmacy benefit manager must prohibit the pharmacy  
148 benefit manager from limiting a pharmacy's or pharmacist's  
149 ability to substitute a less expensive, generically equivalent  
150 drug product for a brand name drug, pursuant to s. 465.025, or  
151 to disclose to a subscriber whether the subscriber's cost-  
152 sharing obligation exceeds the retail price for a covered  
153 prescription drug, and the availability of a more affordable  
154 alternative drug, pursuant to s. 465.0244.

155       (4) A contract between a health maintenance organization  
156 and a pharmacy benefit manager must prohibit the pharmacy  
157 benefit manager from requiring a subscriber to pay for a  
158 prescription drug at the point of sale in an amount greater than  
159 the lesser of:

160           (a) The applicable cost-sharing amount;

161           (b) The allowable claim amount for the prescription drug;

162 and

163           (c) The retail price of the drug in the absence of  
164 prescription drug coverage or programs that otherwise reduce the  
165 cost of a drug to the patient.

166       (5) This section applies to contracts entered into or  
167 renewed on or after July 1, 2018.

168       Section 5. This act shall take effect July 1, 2018.



The Florida Senate

## Committee Agenda Request

**To:** Senator Dana Young, Chair  
Senate Committee on Health Policy

**Subject:** Committee Agenda Request

**Date:** January 12, 2018

---

I respectfully request that SB 1494 on Prescription Drug Pricing Transparency be placed on the:

- committee agenda at your earliest possible convenience.
- next committee agenda.

A handwritten signature in cursive script that reads "Bill Montford".

---

Senator Bill Montford  
Florida Senate, District 3

# APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/6/18  
Meeting Date

1494  
Bill Number (if applicable)

167480  
Amendment Barcode (if applicable)

Topic \_\_\_\_\_

Name Andrew Brown

Job Title President + CEO

Address \_\_\_\_\_  
Street

Phone \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_

Email \_\_\_\_\_

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against

(The Chair will read this information into the record.)

Representing FL Assoc of Health Plans

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.



**THE FLORIDA SENATE**  
**APPEARANCE RECORD**

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/6/18

Meeting Date

1494

Bill Number (if applicable)

Topic Pharmacy Benefit Managers

Amendment Barcode (if applicable)

Name James Wright

Job Title Pharmacy owner

Address 1108 Lake Dr.

Phone 321-806-3951

Street

Cocoa

City

FL

State

32922

Zip

Email Jam

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing Self

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

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S-001 (10/14/14)

# APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2-6-2018

Meeting Date

SB 1494

Bill Number (if applicable)

Topic Prescription Drug Pricing Transparency

Amendment Barcode (if applicable)

Name Bill Minich

Job Title VP PPSC

Address 3375 Capital Circle NE, Suite I

Phone 850-553-3595

Street

Tallahassee

City

FL

State

32308

Zip

Email bill.minich@ppsconline.com

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing \_\_\_\_\_

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

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**THE FLORIDA SENATE**  
**APPEARANCE RECORD**

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/6/2018

SB1494

*Meeting Date*

*Bill Number (if applicable)*

Topic Prescription Drug Pricing Transparency

*Amendment Barcode (if applicable)*

Name Michael A. Jackson

Job Title Executive Vice President and CEO

Address 610 North Adams Street

Phone (850) 222-2400

*Street*

Tallahassee

Florida

32301

Email mjackson@pharmview.com

*City*

*State*

*Zip*

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
*(The Chair will read this information into the record.)*

Representing Florida Pharmacy Association

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

*While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.*

***This form is part of the public record for this meeting.***

S-001 (10/14/14)

**THE FLORIDA SENATE**  
**APPEARANCE RECORD**

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

11/6/10  
Meeting Date

1494  
Bill Number (if applicable)

Topic Pres. Drug Pricing Transparency  
Name Cynthia Henderson

Amendment Barcode (if applicable)

Job Title \_\_\_\_\_

Address 108 E. Jefferson St Suite E  
Street  
Tallahassee FL 32301  
City State Zip

Phone 850-559-0855

Email cynthenderson@me.com

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
*(The Chair will read this information into the record.)*

Representing EPIC Pharmacies

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

*While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.*

**This form is part of the public record for this meeting.**

THE FLORIDA SENATE  
**APPEARANCE RECORD**

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/6/18

Meeting Date

1494

Bill Number (if applicable)

Topic \_\_\_\_\_

Amendment Barcode (if applicable)

Name Chris Nuland

Job Title \_\_\_\_\_

Address 1000 Riverside Ave #240

Phone 904-233-3051

Street

Jacksonville, FL 32210

Email nulandlaw@aol.com

City

State

Zip

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing Florida Chapter, American College of Physicians

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

THE FLORIDA SENATE  
**APPEARANCE RECORD**

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/6/18

Meeting Date

SB 1494

Bill Number (if applicable)

Topic \_\_\_\_\_

Amendment Barcode (if applicable)

Name Jeff Scott

Job Title \_\_\_\_\_

Address 1430 Piedmont Dr. E.

Street

Phone 850 224-6496

Tallahassee

FL

32308

Email j.scott@flmedical.org

City

State

Zip

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing Florida Medical Association

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/6/18  
Meeting Date

1494  
Bill Number (if applicable)

Topic Prescription Drug Pricing Transparency

Amendment Barcode (if applicable)

Name Stephen Winn

Job Title Exec. Director

Address 2544 Blairstone Pines Dr.  
Street

Phone 878-3056

Tallahassee FL 32301  
City State Zip

Email winsr@earthlink.net

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing Florida Osteopathic Medical Association

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

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**THE FLORIDA SENATE**  
**APPEARANCE RECORD**

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/16/18  
Meeting Date

SB 1494  
Bill Number (if applicable)

Topic Prescription Drug Price Transparency

Amendment Barcode (if applicable)

Name Dr. Suzy Wise

Job Title Pharmacist

Address 992 Shetland Ave  
Street

Phone 407 234 1829

Winter Springs FL 32708  
City State Zip

Email SuzyWiseRx@gmail.com

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing \_\_\_\_\_

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

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**THE FLORIDA SENATE**  
**APPEARANCE RECORD**

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2-6-18  
Meeting Date

SB1494  
Bill Number (if applicable)

Topic \_\_\_\_\_

Amendment Barcode (if applicable)

Name PRESTON McDONALD

Job Title PHARMACIST

Address 5740 WESTMONT ROAD  
Street

Phone 850-942-9007

MELTON | FL | 32583  
City State Zip

Email MEPHARM@MEHE.COM

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing \_\_\_\_\_

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

*While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.*

**This form is part of the public record for this meeting.**

**THE FLORIDA SENATE**  
**APPEARANCE RECORD**

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

Feb 6, 18  
Meeting Date

1494  
Bill Number (if applicable)

Topic PBMs

Amendment Barcode (if applicable)

Name Toni Large

Job Title \_\_\_\_\_

Address 519 E. Park Ave  
Street  
Tallahassee, FL 32308  
City State Zip

Phone (850) 556-1461

Email toni@sulaw.net

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing Florida Society of Rheumatology

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

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**THE FLORIDA SENATE**  
**APPEARANCE RECORD**

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/6/18  
Meeting Date

SB 1494  
Bill Number (if applicable)

Topic Pharmacy Budget Management (PBM) Amendment Barcode (if applicable)

Name Kathy Baldwin

Job Title Pharmacist - Immediate Past Presy FSNAP

Address 10117 Barton Village Rd  
Street

Phone 904-755-2335

Jax FL 32258  
City State Zip

Email kathleen.baldwin@bmcjdc.com

Speaking:  For  Against  Information

Waive Speaking:  In Support  Against  
(The Chair will read this information into the record.)

Representing FSTHP Florida Society Health System

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

**The Florida Senate**  
**BILL ANALYSIS AND FISCAL IMPACT STATEMENT**

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

---

Prepared By: The Professional Staff of the Committee on Health Policy

---

BILL: SB 1508

INTRODUCER: Senator Young

SUBJECT: Use of Stem Cells in a Clinic Setting

DATE: February 5, 2018

REVISED: \_\_\_\_\_

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto-Van Winkle	Stovall	HP	<b>Favorable</b>
2.	_____	_____	AP	_____
3.	_____	_____	RC	_____
4.	_____	_____	_____	_____

**I. Summary:**

SB 1508 creates a regulatory framework for the use of stem cells by doctors in a clinic setting. The bill provides definitions for clinic and stem cell and requires clinics to be registered, with certain exceptions. The Department of Health (DOH) must adopt rules for clinic registration and annual inspection. The Board of Medicine (BOM), and the Board of Osteopathic Medicine (BOOM) must adopt rules on advertising, adverse incident reporting, and informed consent.

Each stem cell clinic must have a designated physician who is responsible for complying with all the registration and operation requirements. The clinic must notify the DOH within 10 days following the termination of the designated physician and of the replacement designated physician. The bill gives the DOH authority to suspend a clinic's registration if the clinic fails to have a designated physician practicing at each clinic location. A physician is subject to discipline by his or her medical board if the physician practices in a clinic that is not registered. The bill gives the DOH disciplinary authority to impose fines on the physician or clinic for violating this section, the Florida Drug and Cosmetic Act, and certain provisions of the federal Food, Drug and Cosmetic Act (FDCA). In determining if a penalty is to be imposed, and the amount, the bill delineates specific factors the DOH must consider.

The effective date of the bill is July 1, 2018.

**II. Present Situation:**

**Stem Cells**

Stem cells are unspecialized cells that have the ability to divide for indefinite periods of time in culture median, and to give rise to specialized cells.<sup>1</sup> Stem cells have the potential to develop into

---

<sup>1</sup> National Institutes of Health, Stem Cell Information, Glossary, *Stem Cell* <https://stemcells.nih.gov/glossary.htm#stemcells> (last visited Feb. 4, 2018).

many different types of cells during early life and growth. In addition, in many tissues, stem cells serve as an internal repair system, dividing essentially without limit, to replenish other cells as long as the person is still alive. When a stem cell divides, each new cell has the potential to either remain an undifferentiated stem cell; or become a cell with a specialized function, such as a muscle, red blood, or brain cell.<sup>2</sup>

Stem cells are distinguished from other cells by two important characteristics:

- Stem cells are unspecialized cells capable of renewing themselves through cell division; and
- Stem cells can be induced to become tissue-specific or organ-specific cells, under certain physiologic or experimental conditions.<sup>3</sup>

In some organs, such as the alimentary canal (gut) and bone marrow, stem cells regularly divide to repair and replace worn out or damaged tissues. In other organs, such as the pancreas and the heart, stem cells only divide under special conditions.<sup>4</sup>

Until recently, scientists primarily worked with two kinds of stem cells from animals and humans: embryonic stem cells;<sup>5</sup> and non-embryonic “somatic” or “adult” stem cells.<sup>6</sup> Stem cells offer new potentials for treating diseases such as diabetes and heart disease, given their unique regenerative abilities. However, much work remains to be done in the laboratory and the clinic to understand how to use these cells for cell-based therapies to treat disease. This practice is referred to as regenerative or reparative medicine.<sup>7</sup>

### Federal Regulation of Stem Cells

The U.S. Food and Drug Administration (FDA) has taken the position, under 21 C.F.R. 1271, that certain stem cells are to be labeled a *drug*, and subject to FDA regulation, depending on if the stem cell has been derived from structural tissue or non-structural tissue, in a manufacturing process involving more than minimal manipulation.<sup>8</sup>

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<sup>2</sup>National Institutes of Health, *Stem Cell Basics I.*, <https://stemcells.nih.gov/info/basics/1.htm> (last visited Jan. 10, 2018).

<sup>3</sup> *Id.*

<sup>4</sup> *Id.*

<sup>5</sup> Embryonic stem cells are primitive undifferentiated cells that are derived from preimplantation-stage embryos. They are capable of dividing without differentiating for a prolonged period in culture; and are known to develop into cells and tissues of the three primary germ layers. The three germ layers are the ectoderm, the mesoderm, and the endoderm. See National Institutes of Health, *Stem Cell Information, Glossary, Embryonic Stem Cells*, <https://stemcells.nih.gov/glossary.htm#stemcells> (last visited Jan. 10, 2018).

<sup>6</sup> Somatic (adult) stem cells are relatively rare undifferentiated cells found in many organs and differentiated tissues with a limited capacity for both self-renewal (in the laboratory) and differentiation. Such cells vary in their differentiation capacity, but it is usually limited to cell types in the organ of origin. See National Institutes of Health, *Stem Cell Information, Glossary, Somatic (adult) Stem Cells*, <https://stemcells.nih.gov/glossary.htm#stemcells> (last visited Jan. 10, 2018).

<sup>7</sup> National Institutes of Health, *Stem Cell Basics I.*, <https://stemcells.nih.gov/info/basics/1.htm> (last visited Jan. 10, 2018).

<sup>8</sup> U.S. Department of Health and Human Services, Food and Drug Administration, Center for Evaluation and Research, Center for Devices and Radiological Health, Office of Combination Products, (Nov. 2017, corrected Dec. 2017), *Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use, Guidance for Industry and Food and Drug Administration Staff*, <https://www.fda.gov/downloads/biologicsbloodvaccines/guidancecomplianceregulatoryinformation/guidances/cellularandgenetherapy/ucm585403.pdf> (last visited Jan. 19, 2018). Section 1271.10(a)(1) provides that one of the criteria for an HCT/P to be regulated solely under s. 361 of the PHSA and the regulations in Part 1271, is that the HCT/P is only “minimally manipulated.” As defined in 21 CFR 1271.3(f), “minimal manipulation” means: 1) For *structural tissue*, processing that *does*

The FDA defines a drug as an “article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease” and “articles” (other than food) intended to affect the structure or function of the body.”<sup>9</sup> Under this definition the FDA regulates articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion or transfer into a human recipient as “human cells, tissues, or cellular or tissue-based products (HCT/Ps)” which are stem cells.<sup>10</sup>

The U.S. Center for Biologics Evaluation and Research (CBER) regulates HCT/Ps.<sup>11</sup> Examples of HCT/Ps include, but are not limited to, bone, skin, corneas, ligaments, tendons, muscles, fat, dura mater, heart valves, hematopoietic stem/progenitor cells derived from peripheral and cord blood, oocytes and semen.<sup>12</sup> The CBER does not regulate the transplantation of vascularized human organ transplants such as kidney, liver, heart, lung or pancreas. The Health Resources Services Administration (HRSA) oversees the transplantation of vascularized human organs.<sup>13</sup>

Minimally manipulated bone marrow is also used in stem cell treatments, but not considered by the FDA regulations to be an HCT/Ps,<sup>14</sup> and thus not regulated by the FDA.<sup>15</sup> The Health Resources and Services Administration, an agency of the U.S. Department of Health and Human Services, regulates minimally manipulated bone marrow stem cells uses for transplant.<sup>16</sup>

Because of the unique nature of HCT/Ps, the FDA uses a tiered, risk-based approach to the regulation of HCT/Ps, rather than the Federal Food, Drug and Cosmetic Act (FDCA) for products that meet the definition of a drug, biologic or device.<sup>17</sup> The tiered, risk-based approach

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*not alter the original relevant characteristics of the tissue relating to the tissue’s utility for reconstruction, repair, or replacement (emphasis added); or 2) For cells or nonstructural tissues, processing does not alter the relevant biological characteristics of cells or tissues.* Note: the FDA considers the processing of an HCT/P to be, “more than minimal manipulation,” if information does not exist to show that the HCT/P qualifies for regulation solely under s. 361 of the PHSA. See 21 C.F.R. 1271.21 and 1271.10.

<sup>9</sup> 21 U.S.C. s. 321(g).

<sup>10</sup> 21 C.F.R. 1271.3(d).

<sup>11</sup> See 21 C.F.R., 1270 and 1271. The CBER is a part of the Food and Drug Administration.

<sup>12</sup> The following are not considered HCT/Ps: (1) Vascularized human organs for transplantation; (2) Whole Blood or blood components or blood derivative products subject to listing under 21 C.F.R. ss. 607 and 207, respectively; (3) Secreted or extracted human products, such as milk, collagen, and cell factors, except that semen is considered an HCT/P; (4) Minimally manipulated bone marrow for homologous use and not combined with another article (except for water, crystalloids, or a sterilizing, preserving, or storage agent, if the addition of the agent does not raise new clinical safety concerns with respect to the bone marrow); (5) Ancillary products used in the manufacture of HCT/P; (6) Cells, tissues, and organs derived from animals other than humans; (7) In vitro diagnostic products as defined in 21 C.F.R. s. 809.3(a); and (8) Blood vessels recovered with an organ, as defined in 42 C.F.R. s. 121.2 that are intended for use in organ transplantation and labeled “For use in organ transplantation only.” See also 21 C.F.R. 1271.3(d).

<sup>13</sup> U.S. Food and Drug Administration, *Tissue and Tissue Products*, available at

<https://www.fda.gov/BiologicsBloodVaccines/TissueTissueProducts/default.htm> (last visited Jan. 10, 2018).

<sup>14</sup> See 21 C.F.R. 1271.3(d)(4).

<sup>15</sup> U.S. Food and Drug Administration, Food and Drug Administration, *FDA Warms About Stem Cell Therapies*, <https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm286155.htm> (last visited Jan. 17, 2018).

<sup>16</sup> U.S. Department of Health and Human Services, Health Resources and Services Administration, *Healthcare Systems*, available at <https://www.hrsa.gov/sites/default/files/ourstories/organdonation/factsheet.pdf> (last visited Jan. 19, 2018).

<sup>17</sup> Although the FDA is authorized to apply the requirements in the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to those products that meet the definition of drug, biologic, or device, under this tiered, risk-based approach, those HCT/Ps that meet specific criteria or fall within detailed exceptions do not require premarket review or approval. See U.S. Department of Health and Human Services, Food and Drug Administration, Center for Evaluation and

includes how the transmission of communicable diseases can be prevented; what process controls are necessary to prevent contamination and preserve the integrity and function of the products; and how the clinical safety and effectiveness can be assured.<sup>18</sup>

The tiered, risk-based approach is contained in regulations referred to as the “tissue rules,” issued by the FDA, under the communicable disease authority of s. 361 of the Public Health Service Act (PHSA).<sup>19</sup>

For an HCT/P to be regulated solely under the requirements of s. 361 of the PHSA, and 21 C.F.R. 1271, it must meet all of the following criteria:<sup>20</sup>

- The HCT/P is *minimally manipulated*;<sup>21</sup>
- The HCT/P is intended for homologous use only;<sup>22</sup>
- The HCT/P is not combined with any other article, except water, crystalloids, or a sterilizing, preserving, or storage agent; and
- Either:
  - The HCT/P does not have a systemic effect, and is not dependent upon the metabolic activity of living cells, for its primary function; or
  - The HCT/P has a systemic effect, or is dependent upon the metabolic activity of living cells for its primary function, and:
    - Is for autologous use;<sup>23</sup>
    - Is for allogeneic use;<sup>24</sup> or

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Research, Center for Devices and Radiological Health, Office of Combination Products, Nov. 2017, corrected Dec. 2017, *Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use, Guidance for Industry and Food and Drug Administration Staff*, <https://www.fda.gov/downloads/biologicsbloodvaccines/guidancecomplianceregulatoryinformation/guidances/cellularandgeneotherapy/ucm585403.pdf> (last visited Jan. 19, 2018).

<sup>18</sup> *Id.*

<sup>19</sup> 42 U.S.C. s. 264.

<sup>20</sup> 21 C.F.R. 1271.10.

<sup>21</sup> 21 C.F.R. 1271.10(a)(1) provides that one of the criteria for an HCT/P to be regulated solely under s. 361 of the PHSA and the regulations in 1271, is that the HCT/P is only “minimally manipulated”. As defined in 21 C.F.R. 1271.3(f), “minimal manipulation” means: 1) For *structural tissue*, processing that *does not alter the original relevant characteristics of the tissue relating to the tissue’s utility for reconstruction, repair, or replacement* (emphasis added); or 2) For *cells or nonstructural tissues*, processing *does not alter the relevant biological characteristics of cells or tissues*. Note: the FDA considers the processing of an HCT/P to be, “more than minimal manipulation,” if information does not exist to show that the HCT/P qualifies for regulation solely under s. 361 of the PHSA.

<sup>22</sup> 21 C.F.R. 1271.10(a)(2), provides that one of the criteria for an HCT/P to be regulated solely under s. 361 of the PHSA, and the regulations in 1271, is that the “HCT/P is intended for homologous use only, as reflected by the labeling, advertising, or other indications of the manufacturer’s objective intent.” As defined in 21 C.F.R. 1271.3(c), “homologous use” means the repair, reconstruction, replacement, or supplementation of a recipient’s cells or tissues with an HCT/P that performs the same basic function or functions in the recipient as in the donor. This criterion reflects the FDA’s conclusion that there would be increased safety and effectiveness concerns for HCT/Ps that are intended for a non-homologous use, because there is less basis on which to predict the product’s behavior. *See supra* note 8, at 4.

<sup>23</sup> “*Autologous use*” means the implantation, transplantation, infusion, or transfer of human cells or tissue back into the individual from whom the cells or tissue were recovered. *See* 21 C.F.R. 1271.3(a).

<sup>24</sup> “*Allogeneic use*” means taken from different individuals of the same species. Two or more individuals are said to be allogeneic to one another when the genes at one or more loci are not identical. Medicinenet.com, *Medical Definition of Allogeneic*, <https://www.medicinenet.com/script/main/art.asp?articlekey=25266> (last visited Jan. 10, 2018).

- Is for reproductive use.<sup>25</sup>

To apply the minimally manipulated criteria, the FDA first determines if the HCT/P to be transplanted was derived from structural tissue or cellular/nonstructural tissue. This determination is made based on the characteristics of the HCT/P in the donor, before recovery, and before any processing takes place.<sup>26</sup>

In applying the minimally manipulated analysis the FDA acknowledges that HCT/Ps perform multiple functions; and that structural tissues contain cells. The FDA also acknowledges that some manufacturers assert that an HCT/P has both a structural and cellular/nonstructural function. However, under FDA regulations, HCT/Ps are considered either structural tissues or cells/nonstructural tissues. HCT/Ps that physically support or serve as a barrier or conduit, or connect, cover, or cushion are generally considered structural tissues for the purpose of applying the HCT/P regulatory framework. The FDA gives the following examples of what it considers structural tissue:

- Bone;
- Skin;
- Amniotic membrane and umbilical cord;
- Blood vessel;
- Adipose tissue;
- Articular cartilage;
- Non-articular cartilage; and
- Tendon or ligament.<sup>27</sup>

HCT/Ps that serve metabolic or other biochemical roles in the body such as hematopoietic, immune, and endocrine functions, are generally considered cells/nonstructural tissues for the purpose of applying the FDA HCT/P regulatory framework. The FDA examples of cells or nonstructural tissues include:

- Reproductive cells or tissues (oocytes);
- Hematopoietic stem/progenitor cells (cord blood);
- Lymph nodes and thymus;
- Parathyroid glands;
- Peripheral nerve; and
- Pancreatic tissue.<sup>28</sup>

The FDA defines processing as any activity performed on an HCT/P, other than:

- Rinsing;
- Cleaning;
- Recovery;
- Donor screening;

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<sup>25</sup> 21 C.F.R. 1271.10(a).

<sup>26</sup> *Supra* note 8.

<sup>27</sup> *Id.*

<sup>28</sup> *Supra* note 8.



- Donor testing;
- Storage;
- Sizing;
- Labeling;
- Packaging;
- Distribution;
- Testing for microorganisms;
- Preparation;
- Sterilizations;
- Steps to inactivate or remove adventitious agents;
- Preservation for storage; and
- Removal from storage.<sup>29</sup>

Under this definition, processing includes:

- Cutting;
- Grinding;
- Shaping;
- Culturing;
- Enzymatic digestion; and
- Decellularization.<sup>30</sup>

An HCT/P is exempt from registration and regulation under the PHSA, and 21 C.F.R. 1271, if the establishment:<sup>31</sup>

- Uses the HCT/P's solely for nonclinical scientific or educational purposes;
- Removes HCT/P's from an individual, and implants such HCT/P's into the same individual, during the same surgical procedure;
- Is a carrier who accepts, receives, carries, or delivers HCT/P's in the usual course of business;
- Does not recover, screen, test, process, label, package, or distribute, but only receives or stores HCT/P's, solely for implantation, transplantation, infusion, or transfer within your facility;
- Only recovers reproductive cells or tissue and immediately transfers them into a sexually intimate partner of the cell or tissue donor; or
- If you are an individual under contract with a registered establishment, and engaged solely in recovering cells or tissues and sending the recovered cells or tissues to the registered establishment, you are not required to register or list your HCT/P's independently, but you must comply with all other applicable requirements.<sup>32</sup>

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<sup>29</sup> See 21 C.F.R. 1271.3(ff).

<sup>30</sup> *Supra* note 8.

<sup>31</sup> Establishment means a place of business under one management, at one general physical location, that engages in the manufacture of human cells, tissues, and cellular and tissue-based products. Establishment includes: (1) Any individual, partnership, corporation, association, or other legal entity engaged in the manufacture of human cells, tissues, and cellular and tissue-based products; and (2) Facilities that engage in contract manufacturing services for a manufacturer of human cells, tissues, and cellular and tissue-based products. 21 C.F.R. 1271.3(b).

<sup>32</sup> 21 C.F.R. 1271.15.

If an HCT/P does not meet the above criteria, and the manufacturer of the HCT/P does not qualify for an exception,<sup>33</sup> the HCT/P will be regulated as a drug, device, and/or biological product under the FDCA, the PHSA,<sup>34</sup> and applicable regulations;<sup>35</sup> and premarket review will be required.<sup>36</sup>

According to the FDA, if a manufacturer/establishment isolates cells from structural tissue to produce a cellular therapy product, the definition of minimal manipulation applies, regardless of the method used to isolate the cells. This is because the assessment of whether the HCT/P is a structural tissue or cellular/nonstructural tissue is based on the characteristics of the HCT/P as it exists in the donor, prior to recovery, and prior to any processing that takes place.<sup>37</sup>

The federal law requires tissue establishments<sup>38</sup> that do not meet an exemption, to:

- Screen and test donors;
- Prepare and follow written procedures for the prevention of the spread of communicable disease; and
- Maintain records.<sup>39</sup>

The FDA has published rules to broaden the scope of products subject to regulation, and to include more comprehensive requirements, to prevent the introduction, transmission and spread of communicable disease. Those rules include requiring the tissue establishments to:

- Register and submit a list to the FDA of every HCTP it manufactures within five days after operations begin, or within 30 days of the effective date of the registration;<sup>40</sup>
- Determine donor eligibility, including screening and testing;<sup>41</sup> and
- To recover, process, store, label, package, and distribute HCT/Ps, and screen and test cell and tissue donors, in such a way that prevents the introduction, transmission, or spread of communicable diseases.<sup>42</sup>

The requirements are intended to improve protection of the public health while minimizing regulatory burden.<sup>43</sup>

The only HCT/Ps that are FDA-approved for use in the United States consist of blood-forming stem cells (hematopoietic progenitor cells) derived from cord blood. These products are approved for limited use in patients with disorders that affect the body system that is involved in

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<sup>33</sup> 21 C.F.R., 1271.10, 1271.15 and 1271.155.

<sup>34</sup> 42 U.S.C. s. 262.

<sup>35</sup> 21 C.F.R.1271.

<sup>36</sup> *Supra* note 8.

<sup>37</sup> *Id.*

<sup>38</sup> *Supra* note 31.

<sup>39</sup> *See* 21 C.F.R 1270 and 1271.2121.

<sup>40</sup> 21 C.F.R. 1271.21.

<sup>41</sup> 21 C.F.R. 1271.45.

<sup>42</sup> *Id.*

<sup>43</sup> U.S. Department of Health and Human Services, Food and Drug Administration, *Tissue and Tissue Products*, <https://www.fda.gov/BiologicsBloodVaccines/TissueTissueProducts/default.htm> (last visited Jan. 10, 2018).

the production of blood (called the “hematopoietic” system). The FDA-approved stem cell products are listed on the FDA website.<sup>44</sup>

### ***Stem Cells from Adipose Tissue***

Structural HCT/Ps include cells obtained from adipose tissue. Adipose tissue is typically defined as a connective tissue that stores energy in the form of lipids, insulates the body, and provides cushioning and support for subcutaneous tissues and internal organs. It is composed of clusters of cells (adipocytes) surrounded by a reticular fiber network and interspersed small blood vessels, divided into lobes and lobules by connective tissue septa.<sup>45</sup> Additionally, adipose tissue contains other cells, including pre-adipocytes, fibroblasts, vascular endothelial cells, and a variety of immune cells.<sup>46</sup>

The FDA, by way of example, specifically addresses the original relevant characteristics of adipose tissue relating to its utility to provide cushioning and support, which includes its bulk and lipid storage capacity. A manufacturer that recovers adipose tissue by tumescent liposuction and processes (e.g., enzymatically digests, mechanically disrupts, etc.) the adipose tissue to isolate cellular components (with or without subsequent cell culture or expansion), to stromal vascular fraction (SVF), is considered by the FDA to be more than minimally manipulating the HCT/P. This is because the processing breaks down and eliminates the adipocytes and the surrounding structural components that provide cushioning and support, thereby altering the original relevant characteristics of the HCT/P, relating to its utility for reconstruction, repair, or replacement.<sup>47</sup>

The FDA treats the recovery of adipose tissue from a donor for allogenic or autologous use, the recovery of a structural tissue. If the adipose tissue is then processed through enzymatic digestion, mechanical disruption etc., to isolate non-adipocyte, or non-structural components, from the adipose tissue (with or without subsequent cell culture or expansion), the processing of the structural tissues becomes stromal vascular fraction (SVF), and is considered more than minimally manipulated.<sup>48</sup> If the SVF is then administered intravenously or intrathecally, to a recipient to treat a variety of diseases or conditions, it will not be solely regulated the PHSA.<sup>49</sup>

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<sup>44</sup> U.S. Department of Health and Human Services, Food and Drug Administration, *Approved Cellular and Gene Therapy Products*, (page last updated Feb. 2, 2018) available at <https://www.fda.gov/biologicsbloodvaccines/cellulargenetherapyproducts/approvedproducts/default.htm> (last visited Jan. 18, 2018).

<sup>45</sup> Some HCT/Ps from adipose tissue may also be regulated as devices. For more information about device regulation, See CDRH's webpage *Device Advice – Overview of Medical Device Regulation*, (page last updated Aug. 14, 2015) available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/default.htm> (last visited Jan.10, 2018).

<sup>46</sup> Brown SA, Levi, B, Lequeux, C, et al. Plastic Reconstructive Surgery, *Basic Science Review on Adipose Tissue for Clinicians*, 126:1936, 2010.

<sup>47</sup> *Supra* note 8.

<sup>48</sup> This is because the connective tissue and structural components of the adipose tissue are entirely removed from the non-adipocyte or non-structural isolates, and thus altering the original relevant characteristics relating to the tissues utility for reconstruction, repair, and replacement. See *supra* note 8 and 21 C.F.R. 1271.3(f)(1).

<sup>49</sup> 42 U.S.C. 264 and s. 301 PHSA.

## Florida Regulation of Stem Cells

### *Stem Cell Preparation/Manufacturing*

The Department of Business and Professional Regulation (DBPR) administers and enforces the Florida Drug and Cosmetic Act (FDCA) to prevent fraud, adulteration, misbranding, or false advertising in the preparation, manufacture, repackaging, or distribution of drugs, devices, and cosmetics.<sup>50</sup> In Florida, “a person may not sell, offer for sale, hold for sale, manufacture, repackage, distribute, or give away any new drug unless an approved application has become effective under the federal act or unless otherwise permitted by the Secretary of the United States Department of Health and Human Services for shipment in interstate commerce.”<sup>51</sup>

The FDCA defines a “drug” as an article that is:

- Recognized in the current edition of the United States Pharmacopoeia and National Formulary (USP-FM),<sup>52</sup> official Homeopathic Pharmacopoeia of the United States (HPUS),<sup>53</sup> or any supplement to any of those publications;
- Intended for use in the diagnosis, cure, mitigation, treatment, therapy, or prevention of disease in humans or other animals;
- Intended to affect the structure or any function of the body of humans or other animals; or
- Intended for use as a component of any article specified in paragraph (a), paragraph (b), or paragraph (c), and includes active pharmaceutical ingredients,<sup>54</sup> but does not include devices or their nondrug components, parts, or accessories.<sup>55</sup>

The FDCA defines the manufacturing of a drug to mean the preparation, deriving, compounding, propagation, processing, producing, or fabrication of a substance into a drug.<sup>56</sup> Under the Act a manufacturer of a drug is a person, co-licensed partner, or affiliate, of a person who holds a New Drug Application, an Abbreviated New Drug Application, a Biologics License Application, or a New Animal Drug Application approved or licensed under the federal Public Health Service Act<sup>57</sup> for such drug or biologics, or if such drug or biologics are not the subject of an approved application or license, the person who manufactured the drug or biologics.

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<sup>50</sup> See part I of ch. 499, F.S.

<sup>51</sup> Section 499.023, F.S.

<sup>52</sup> USP-NF is a combination of two compendia, the United States Pharmacopoeia (USP) and the National Formulary (NF). It contains standards for medicines, dosage forms, drug substances, excipients, biologics, compounded preparations, medical devices, dietary supplements, and other therapeutics. See 21 U.S.C. s. 301(g)(1).

<sup>53</sup> The HPUS is declared a legal source of information on drug products (along with the USP/NF) in the Federal Food Drug and Cosmetic Act, 21 U.S.C. § 301. Section 201(g)(1) of the Act. 21 U.S.C. s. 321 defines the term “drug” as articles recognized in the official United States Pharmacopoeia, official Homœopathic Pharmacopœia of the United States, or official National Formulary or any supplement to any of them.

<sup>54</sup> Section 499.003(1), F.S., defines an “active pharmaceutical ingredient” includes any substance or mixture of substances intended, represented, or labeled for use in drug manufacturing that furnishes or is intended to furnish, in a finished dosage form, any pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, therapy, or prevention of disease in humans or other animals, or to affect the structure or any function of the body of humans or animals.

<sup>55</sup> Section 499.003(18), F.S.

<sup>56</sup> Section 499.003(28), F.S.

<sup>57</sup> 42 U.S.C. s. 262.

Stem cells recovered, processed, and implanted in Florida that fit the above definitions, are “unapproved new drugs” under both federal and state regulation; and require a manufacturing permit issued by the DBPR to ensure that the drugs are manufactured in accordance with good manufacturing practices.<sup>58</sup>

### ***Stem Cell Implantation or Transplantation***

Stem cells may be collected, processed, and implanted or transplanted in a physician’s office, health care clinic, ambulatory surgical center, or a hospital.

### **Physician’s Office**

The DOH Office of Surgery Registration and Inspection Program, was established to register and set standards for allopathic and osteopathic physicians performing surgery in an office setting. The DOH requires all physicians who perform the following to register their office with the DOH:

- Liposuction procedures where more than 1,000 cubic centimeters of supernatant fat is removed;
- Level II procedures lasting more than five minutes; and
- All Level III surgical procedures.<sup>59</sup>

The DOH will inspect those registered, that are not nationally accredited, to ensure the safety of the people of Florida.<sup>60</sup>

Under current regulations, it is unclear whether stem cell implantation or transplantation in physicians’ offices is subject to inspection and regulation by the DOH. Hypothetically, if the physician performs a procedure by removing less than 4000 cc of supernatant fat, uses no sedation, and the procedure lasts less than five minutes, it is not subject to the DOH regulation.<sup>61</sup>

### **Health Care Clinics**

The Health Care Clinic Act,<sup>62</sup> provides the Agency for Health Care Administration (AHCA) with licensing and regulatory authority to provide standards and oversight for health care clinics.<sup>63</sup> A clinic is defined as an entity where health care services are provided and which tenders charges for reimbursement for such services. Numerous exceptions to licensure exist.<sup>64</sup>

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<sup>58</sup> Department of Business and Professional Regulation, Division of Drugs, Devices and Cosmetics, *Does my company need a permit?* available at <http://www.myfloridalicense.com/dbpr/ddc/ProgramFAQ1.html> (last visited Jan. 18, 2018). See also ss. 458.309(3) and 458.351, F.S.; Rule 64B8-9.009, F.A.C.

<sup>59</sup> Department of Business and Professional Regulation, Division of Drugs, Devices and Cosmetics, *Does my company need a permit?* available at <http://www.myfloridalicense.com/dbpr/ddc/ProgramFAQ1.html> (last visited Jan. 18, 2018). See also ss. 458.309(3) and 458.351, F.S.; Rule 64B8-9.009, F.A.C.

<sup>60</sup> The Department of Health, Licensing and Regulation, *Office Surgery Registration*, <http://www.floridahealth.gov/licensing-and-regulation/office-surgery-registration/index.html> (last visited Jan. 22, 2018).

<sup>61</sup> See Rule 64B8-9.9009, F.A.C.

<sup>62</sup> Part X of ch. 400, F.S.

<sup>63</sup> Section 400.990, F.S.

<sup>64</sup> Section 400.9905(4), F.S.

The AHCA interprets this phrase to solely include entities that bill third parties, such as Medicare, Medicaid, and insurance companies. Entities that provide health care services and accept “cash only” for services are excluded from the definition of “clinic” and are not subject to licensure or regulation by the AHCA.<sup>65</sup>

### **Hospitals and Ambulatory Surgical Centers**

The AHCA is responsible for licensing, registering, and regulating hospitals and Ambulatory Surgical Centers (ASC) pursuant to ch. 395, F.S.<sup>66</sup>

An ASC is a facility, not a part of a hospital, that has as its primary purpose to provide elective surgical care, in which the patient is admitted and discharged in the same working day, and is not permitted to stay overnight.

### **Regulation of Physicians in Florida**

The BOM and the BOOM (the boards), within the DOH, have the authority to adopt rules to regulate the practice of medicine and osteopathic medicine, respectively. The boards have authority to establish, by rule, standards of practice and standards of care for particular settings.<sup>67</sup> Such standards may include education and training, medications including anesthetics, assistance of and delegation to other personnel, sterilization, performance of complex or multiple procedures, records, informed consent, and policy and procedures manuals.<sup>68</sup>

Currently the BOM is warning physicians and consumers that they should be aware of the risks involved in stem cell therapies and regenerative medicine that have not been FDA approved.<sup>69</sup> The BOM warns physicians providing stem cell treatment that he or she should have an investigational new drug application (IND) or a single patient IND for Compassionate or Emergency Use.<sup>70</sup> Florida does not specifically regulate clinics that perform treatments using stem cells; but the Boards have authority to investigate and discipline physicians who fail to meet the standard of care for providing any medical services. In 2013, the Board of Medicine revoked the licenses of two physicians in administrative cases involving stem cells for failing to meet the standard of care.<sup>71</sup>

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<sup>65</sup> Agency for Health Care Administration, *Ambulatory Surgical Centers* [http://ahca.myflorida.com/MCHQ/Health\\_Facility\\_Regulation/Hospital\\_Outpatient/ambulatory.shtml](http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Hospital_Outpatient/ambulatory.shtml) (last visited Feb. 1, 2018).

<sup>66</sup> Section 395.002(3), F.S.

<sup>67</sup> Sections 458.331(v) and 459.015(z), F.S.

<sup>68</sup> *Id.*

<sup>69</sup> The Department of Health, Board of Medicine, *Information on Stem Cell Clinics Offering Unapproved Therapies*, <http://flboardofmedicine.gov/latest-news/october-2015-newsletter/> (last visited Jan. 31 2018).

<sup>70</sup> *Id.*

<sup>71</sup> Department of Health, *Senate Bill 1508 Analysis* (Jan. 11, 2018) (on file with the Senate Committee on Health Policy).

### III. Effect of Proposed Changes:

#### Stem Cell Clinic Registration and Regulation

The bill requires a clinic or physician who advertises, uses, or purports to use stem cells or products containing stems cells to register with the DOH.

The bill defines a clinic as a privately or publicly owned facility or office that:

- Advertises a service that uses, or purports to use, stem cells or a product containing stem cells to diagnose, cure, mitigate, treat, provide therapy for, or prevent an injury or disease; or
- Performs any procedure that is intended to diagnose, cure, mitigate, treat, provide therapy for, or prevent an injury or disease that uses, or purports to use, stem cells or a product containing stem cells which has not been approved by, or is not the subject of a clinical trial approved of by the FDA.

The bill defines a stem cell as allogenic or autologous cell that has been altered or processed to become undifferentiated, losing its original structural function, so that it can become differentiated into a specialized cell type. The definition excludes cells that are only rinsed, cleaned, or sized and remain differentiated. A clinic does not have to register with the DOH if it:

- Is licensed under ch. 395, F.S.;<sup>72</sup>
- Is wholly owned and operated by one or more Florida-licensed physicians;
- Is affiliated with an accredited medical school that provides training to medical students, residents, or fellows; or
- Solely performs one or more of the following:
  - Collection of umbilical cord blood cells for blood banking;
  - Collection, transfer, or insemination of oocytes; or
  - Injection or infusion of platelet-rich plasma.

Each clinic must be registered separately. A clinic or physician must submit a new registration if there is a change of ownership. The bill requires each clinic to designate a physician who holds a full, active and unencumbered Florida license to be responsible for compliance with clinic registration and operation requirements.

A clinic must notify the DOH within ten days of a change in the designated physician. If a clinic fails to have a designated physician, the DOH may issue an emergency suspension<sup>73</sup> of the clinic's registration.

The bill authorizes the DOH to impose a fine of up to \$5,000 per violation if the clinic fails to comply with the registration requirement, the DOH and Board rules, the Florida Drug and Cosmetic Act,<sup>74</sup> or the federal Food, Drug, and Cosmetic Act.<sup>75</sup> When determining if a fine should be imposed, and the amount of the fine, the DOH must consider:

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<sup>72</sup> Chapter 395, F.S., governs the licensure and regulation of hospitals and surgery centers.

<sup>73</sup> The DOH may issue an emergency suspension, restriction, or limitation of a license if it finds that an immediate serious danger to the public health, safety, welfare exists.

<sup>74</sup> Chapter 499, F.S.

<sup>75</sup> 21 U.S.C. ss. 301 and 25, Stat. 1040 et seq.

- The gravity of the violation, including the existence and severity of patient deception, serious or physical mental harm, or the potential of such deception or harm;
- The actions taken by the physician, clinic, or designated physician to correct the violation;
- Whether there were previous violations at the clinic; and
- The financial benefits derived by the physician, clinic, or designated physician from committing or continuing to commit the violation.

If the physician, clinic, or designated physician fails to cease the violating behavior as of the date required by the DOH, each day the violation continues constitutes an additional, separate, and distinct violation. The DOH may impose a fine if the designated physician knowingly misrepresents that action had been taken to correct a violation. However, if it is an owner-operated clinic, the DOH may impose a fine and revoke or deny a clinic registration.

The bill requires the DOH to adopt rules for the implementation of the registration requirement, as well as an annual inspection of registered clinics. All costs for the registration and inspections must be borne by the clinic. The Boards must adopt rules regarding advertising, adverse incident reporting, and informed consent guidelines for the use, or purported use, of stem cells or products containing stem cells in a clinic required to register.

### **Physician Responsibilities**

The bill requires a physician who performs a procedure using or purporting to use stem cells or products containing stem cells to follow the applicable good manufacturing practices for collecting, removing, processing, implanting, and transferring stem cells or products containing stems cells, pursuant to the federal Food, Drug, and Cosmetic Act<sup>76</sup> and federal law governing human cells, tissues, and cellular and tissue-based products.<sup>77</sup>

A physician who practices at a clinic that is not registered as required may be disciplined by his or her Board.

The bill provides an effective date of July 1, 2018.

## **IV. Constitutional Issues:**

### **A. Municipality/County Mandates Restrictions:**

None.

### **B. Public Records/Open Meetings Issues:**

None.

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<sup>76</sup> 21 U.S.C. ss. 301, et seq., and 52 Stat. 1040 et seq.

<sup>77</sup> 21 C.F.R. s. 1271.



C. Trust Funds Restrictions:

None.

**V. Fiscal Impact Statement:**

A. Tax/Fee Issues:

The DOH will experience an increase in revenue associated with the registration and inspections of clinics that use stem cells. SB 1508 provides that the person or entity that wants to register and operate a clinic must pay all cost for registration and inspection. The DOH estimates approximately 20 clinics would register initially.

B. Private Sector Impact:

None.

C. Government Sector Impact:

The DOH will experience a recurring increase in costs and workload associated with the registration, regulation, and inspections for clinics that use stem cells. Current budget authority is adequate to absorb this impact.

**VI. Technical Deficiencies:**

None.

**VII. Related Issues:**

None.

**VIII. Statutes Affected:**

This bill creates the following sections of the Florida Statutes: 458.352, 459.027.

**IX. Additional Information:**

A. Committee Substitute – Statement of Changes:

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.

By Senator Young

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1                                   A bill to be entitled  
2       An act relating to the use of stem cells in a clinic  
3       setting; creating ss. 458.352 and 459.027, F.S.;  
4       defining the terms "clinic" and "stem cell"; requiring  
5       a physician or osteopathic physician or a clinic owner  
6       to register a clinic with the Department of Health if  
7       the clinic meets certain criteria; specifying that  
8       each clinic location must be registered separately and  
9       must designate a physician to be responsible for  
10      complying with certain requirements; requiring the  
11      clinic to notify the department of a change of  
12      designated physician within a specified timeframe;  
13      providing that summary suspension of a clinic's  
14      registration certificate may occur if a designated  
15      physician or designated osteopathic physician is not  
16      practicing at the clinic location; prohibiting a  
17      physician from practicing medicine or an osteopathic  
18      physician from practicing osteopathic medicine in a  
19      certain clinic that is not registered with the  
20      department; specifying certain disciplinary action for  
21      violations; requiring a physician or osteopathic  
22      physician to adhere to specified regulations in the  
23      performance of any procedure using or purporting to  
24      use stem cells or products containing stem cells;  
25      requiring the department to adopt rules to administer  
26      registration and an annual inspection of registered  
27      clinics; specifying that a person or entity seeking to  
28      register and operate a clinic must pay all costs of  
29      registration and inspection; authorizing the

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30 department to impose fines on a physician or  
31 osteopathic physician or clinic that violates  
32 specified requirements; requiring the Board of  
33 Medicine and the Board of Osteopathic Medicine,  
34 respectively, to adopt certain rules and guidelines;  
35 authorizing the department to impose certain fines;  
36 requiring the department to consider certain factors  
37 in determining the imposition of such a fine;  
38 authorizing the department to impose a fine and revoke  
39 or deny a clinic registration in certain  
40 circumstances; requiring the imposition of certain  
41 fines for specified violations of clinic registration  
42 requirements; providing an effective date.

43  
44 Be It Enacted by the Legislature of the State of Florida:

45  
46 Section 1. Section 458.352, Florida Statutes, is created to  
47 read:

48 458.352 Use of stem cells in a clinic setting.-

49 (1) DEFINITIONS.-As used in this section, the term:

50 (a) "Clinic" means a publicly or privately owned facility  
51 or office that:

52 1. Advertises for any service that uses, or purports to  
53 use, stem cells or any product containing stem cells that is  
54 intended to diagnose, cure, mitigate, treat, provide therapy  
55 for, or prevent an injury or a disease; or

56 2. Performs any procedure that is intended to diagnose,  
57 cure, mitigate, treat, provide therapy for, or prevent an injury  
58 or a disease that uses, or purports to use, stem cells or any

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59 product containing stem cells which has not been approved by the  
60 United States Food and Drug Administration or is not the subject  
61 of a clinical trial approved by the United States Food and Drug  
62 Administration.

63 (b) "Stem cell" means an allogenic or autologous cell that  
64 is altered or processed to become undifferentiated, losing its  
65 original structural function, so that it can become  
66 differentiated into a specialized cell type. The term does not  
67 include cells that are only rinsed, cleaned, or sized and remain  
68 differentiated.

69 (2) REGISTRATION.—

70 (a) A physician or clinic owner who advertises, uses, or  
71 purports to use stem cells or products containing stem cells in  
72 a clinic must register the clinic with the department, unless  
73 any of the following apply:

74 1. The clinic is a facility licensed under chapter 395;

75 2. The clinic is wholly owned and operated by one or more  
76 physicians licensed under this chapter or chapter 459;

77 3. The clinic is affiliated with an accredited medical  
78 school that provides training to medical students, residents, or  
79 fellows; or

80 4. The clinic solely performs one or more of the following  
81 procedures:

82 a. The collection of umbilical cord blood cells for blood  
83 banking;

84 b. The collection, transfer, or insemination of oocytes; or

85 c. The injection or infusion of platelet-rich plasma.

86 (b) Each clinic location must be registered separately.

87 (c) As a part of registration, a clinic must designate a

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88 physician who is responsible for complying with all requirements  
89 related to registration and operation of the clinic in  
90 compliance with this section. Within 10 days after termination  
91 of a designated physician, the clinic must notify the department  
92 of the identity of another designated physician for that clinic.  
93 A designated physician must have a full, active, and  
94 unencumbered license issued under this chapter or chapter 459  
95 and must practice at the clinic location for which he or she has  
96 assumed responsibility. Failing to have a licensed designated  
97 physician practicing at the location of the registered clinic  
98 may be the basis for a summary suspension of the clinic  
99 registration certificate as described in s. 456.073(8) for a  
100 license or in s. 120.60(6).

101 (3) PHYSICIAN RESPONSIBILITIES.—

102 (a) A physician may not practice medicine in a clinic that  
103 is not registered with the department as required by this  
104 section or s. 459.027. A physician who violates this paragraph  
105 is subject to disciplinary action by his or her appropriate  
106 medical regulatory board.

107 (b) In the performance of any procedure using or purporting  
108 to use stem cells or products containing stem cells, the  
109 physician shall adhere to the applicable current good  
110 manufacturing practices for the collection, removal, processing,  
111 implantation, and transfer of stem cells, or products containing  
112 stem cells, pursuant to the Federal Food, Drug, and Cosmetic  
113 Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq.; and 21  
114 C.F.R. 1271, Human Cells, Tissues, and Cellular and Tissue-Based  
115 Products.

116 (4) RULEMAKING.—

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117 (a) The department shall adopt rules necessary to  
118 administer registration and an annual inspection of registered  
119 clinics. The person or entity seeking to register and operate  
120 the clinic must pay all costs of registration and inspection.

121 (b) The board shall adopt rules regarding advertising,  
122 adverse incident reporting, and informed consent guidelines for  
123 the use or purported use of stem cells or products containing  
124 stem cells in a clinic required to register under this section.

125 (5) PENALTIES; ENFORCEMENT.—

126 (a) The department may impose an administrative fine on a  
127 physician or a clinic of up to \$5,000 per violation for  
128 violating the requirements of this section; chapter 499, the  
129 Florida Drug and Cosmetic Act; the Federal Food, Drug, and  
130 Cosmetic Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq.;  
131 21 C.F.R. 1271, Human Cells, Tissues, and Cellular and Tissue-  
132 Based Products; or the rules of the department. In determining  
133 whether a penalty is to be imposed, and in fixing the amount of  
134 the fine, the department shall consider the following factors:

135 1. The gravity of the violation, including the probability  
136 that patient deception, or serious physical or emotional harm,  
137 has resulted or could have resulted; the severity of the  
138 deception, harm, or potential harm; and the extent to which the  
139 provisions of the applicable laws or rules were violated.

140 2. What actions, if any, the physician, clinic owner, or  
141 designated physician took to correct the violations.

142 3. Whether there were any previous violations at the  
143 clinic.

144 4. The financial benefits that the physician, clinic, or  
145 designated physician derived from committing or continuing to

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146 commit the violation.

147 (b) Each day a violation continues after the date fixed for  
148 termination of the violation as ordered by the department  
149 constitutes an additional, separate, and distinct violation.

150 (c) The department may impose a fine and, in the case of an  
151 owner-operated clinic, revoke or deny a clinic registration if  
152 the clinic's designated physician knowingly misrepresents  
153 actions taken to correct a violation.

154 (d) A physician, clinic, or designated physician that  
155 concurrently operates an unregistered clinic is subject to an  
156 administrative fine of \$5,000 per day for each clinic location.

157 (e) If the physician or owner of a clinic that is required  
158 to register fails to apply to register upon a change of  
159 ownership and operates the clinic under the new ownership, the  
160 new owner is also subject to a fine of \$5,000 per day for each  
161 location.

162 Section 2. Section 459.027, Florida Statutes, is created to  
163 read:

164 459.027 Use of stem cells in clinic setting.-

165 (1) DEFINITIONS.-As used in this section, the term:

166 (a) "Clinic" means a publicly or privately owned facility  
167 or office that:

168 1. Advertises for any service that uses, or purports to  
169 use, stem cells or any product containing stem cells that is  
170 intended to diagnose, cure, mitigate, treat, provide therapy  
171 for, or prevent an injury or a disease; or

172 2. Performs any procedure that is intended to diagnose,  
173 cure, mitigate, treat, provide therapy for, or prevent an injury  
174 or a disease that uses, or purports to use, stem cells or any

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175 product containing stem cells which has not been approved by the  
176 United States Food and Drug Administration or is not the subject  
177 of a clinical trial approved by the United States Food and Drug  
178 Administration.

179 (b) "Stem cell" means an allogenic or autologous cell that  
180 is altered or processed to become undifferentiated, losing its  
181 original structural function, so that it can become  
182 differentiated into a specialized cell type. The term does not  
183 include cells that are only rinsed, cleaned, or sized and remain  
184 differentiated.

185 (2) REGISTRATION.—

186 (a) An osteopathic physician or clinic owner who  
187 advertises, uses, or purports to use stem cells or products  
188 containing stem cells in a clinic must register the clinic with  
189 the department, unless any of the following apply:

190 1. The clinic is a facility licensed under chapter 395;

191 2. The clinic is wholly owned and operated by one or more  
192 physicians licensed under this chapter or chapter 458;

193 3. The clinic is affiliated with an accredited medical  
194 school that provides training to medical students, residents, or  
195 fellows; or

196 4. The clinic solely performs one or more of the following  
197 procedures:

198 a. The collection of umbilical cord blood cells for blood  
199 banking;

200 b. The collection, transfer, or insemination of oocytes; or

201 c. The injection or infusion of platelet-rich plasma.

202 (b) Each clinic location must be registered separately.

203 (c) As a part of registration, a clinic must designate a



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204 physician who is responsible for complying with all requirements  
205 related to registration and operation of the clinic in  
206 compliance with this section. Within 10 days after termination  
207 of a designated physician, the clinic must notify the department  
208 of the identity of another designated physician for that clinic.  
209 A designated physician must have a full, active, and  
210 unencumbered license issued under this chapter or chapter 458  
211 and must practice at the clinic location for which he or she has  
212 assumed responsibility. Failing to have a licensed designated  
213 physician practicing at the location of the registered clinic  
214 may be the basis for a summary suspension of the clinic  
215 registration certificate as described in s. 456.073(8) for a  
216 license or in s. 120.60(6).

217 (3) PHYSICIAN RESPONSIBILITIES.—

218 (a) An osteopathic physician may not practice osteopathic  
219 medicine in a clinic that is not registered with the department  
220 as required by this section or s. 458.352. An osteopathic  
221 physician who violates this paragraph is subject to disciplinary  
222 action by his or her appropriate medical regulatory board.

223 (b) In the performance of any procedure using or purporting  
224 to use stem cells or products containing stem cells, the  
225 osteopathic physician shall adhere to the applicable current  
226 good manufacturing practices for the collection, removal,  
227 processing, implantation, and transfer of stem cells, or  
228 products containing stem cells, pursuant to the Federal Food,  
229 Drug, and Cosmetic Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040  
230 et seq.; and 21 C.F.R. 1271, Human Cells, Tissues, and Cellular  
231 and Tissue-Based Products.

232 (4) RULEMAKING.—

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233 (a) The department shall adopt rules necessary to  
234 administer registration and an annual inspection of registered  
235 clinics. The person or entity seeking to register and operate  
236 the clinic must pay all costs of registration and inspection.

237 (b) The board shall adopt rules regarding advertising,  
238 adverse incident reporting, and informed consent guidelines for  
239 the use or purported use of stem cells or products containing  
240 stem cells in a clinic required to register under this section.

241 (5) PENALTIES; ENFORCEMENT.—

242 (a) The department may impose an administrative fine on an  
243 osteopathic physician or a clinic of up to \$5,000 per violation  
244 for violating the requirements of this section; chapter 499, the  
245 Florida Drug and Cosmetic Act; the Federal Food, Drug, and  
246 Cosmetic Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq.;  
247 21 C.F.R. 1271, Human Cells, Tissues, and Cellular and Tissue-  
248 Based Products; or the rules of the department. In determining  
249 whether a penalty is to be imposed, and in fixing the amount of  
250 the fine, the department shall consider the following factors:

251 1. The gravity of the violation, including the probability  
252 that patient deception, or serious physical or emotional harm,  
253 has resulted or could have resulted; the severity of the  
254 deception, harm, or potential harm; and the extent to which the  
255 provisions of the applicable laws or rules were violated.

256 2. What actions, if any, the osteopathic physician, clinic  
257 owner, or designated physician took to correct the violations.

258 3. Whether there were any previous violations at the  
259 clinic.

260 4. The financial benefits that the osteopathic physician,  
261 clinic, or designated physician derived from committing or

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262 continuing to commit the violation.

263 (b) Each day a violation continues after the date fixed for  
264 termination of the violation as ordered by the department  
265 constitutes an additional, separate, and distinct violation.

266 (c) The department may impose a fine and, in the case of an  
267 owner-operated clinic, revoke or deny a clinic registration if  
268 the clinic's designated physician knowingly misrepresents  
269 actions taken to correct a violation.

270 (d) An osteopathic physician, clinic, or designated  
271 physician that concurrently operates an unregistered clinic is  
272 subject to an administrative fine of \$5,000 per day for each  
273 clinic location.

274 (e) If the osteopathic physician or owner of a clinic that  
275 is required to register fails to apply to register upon a change  
276 of ownership and operates the clinic under the new ownership,  
277 the new owner is also subject to a fine of \$5,000 per day for  
278 each location.

279 Section 3. This act shall take effect July 1, 2018.



## THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

**COMMITTEES:**  
Commerce and Tourism, *Chair*  
Communications, Energy, and Public Utilities,  
*Vice Chair*  
Appropriations  
Appropriations Subcommittee on Pre-K - 12  
Education  
Health Policy  
Rules

**SENATOR BILL MONTFORD**  
3rd District

February 5, 2018

Senator Dana Young, Chair  
Senate Committee on Health Policy  
530 Knott Building  
Tallahassee, Florida 32399-1100

Dear Senator Young:

I respectfully request to be excused from the Senate Health Policy Committee meeting scheduled for February 6, 2018.

Your consideration is greatly appreciated.

Sincerely,

A handwritten signature in cursive script that reads "Bill Montford".

William "Bill" Montford  
State Senate, District 3

WM/md

A large, stylized handwritten signature in black ink, written over a horizontal line. The signature is highly cursive and difficult to decipher.

**REPLY TO:**

- 410 Senate Office Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5003
- 20 East Washington Street, Suite D, Quincy, Florida 32351 (850) 627-9100
- 105 North Jefferson Street, Perry, Florida 32347 (850) 223-0902

Senate's Website: [www.flsenate.gov](http://www.flsenate.gov)

**JOE NEGRON**  
President of the Senate

**ANITERE FLORES**  
President Pro Tempore

# CourtSmart Tag Report

Room: KN 412

Case No.:

Type:

Caption: Senate Health Policy Committee

Judge:

Started: 2/6/2018 11:08:36 AM

Ends: 2/6/2018 12:21:42 PM

Length: 01:13:07

11:08:41 AM Call to order  
11:08:43 AM Roll Call  
11:09:03 AM Pledge of Allegiance  
11:09:53 AM Tab 4 SB 848  
11:09:56 AM Sen Grimsley  
11:10:12 AM AM 443488  
11:10:32 AM Sen Grimsley  
11:12:32 AM AM 443488 Adopted  
11:12:56 AM Bill Mincy, Small Business Pharmacy Owners, Waives in opposition  
11:13:00 AM James Wright, Pharmacy Owner, Waives in opposition  
11:13:15 AM Michael Mone, Cardinal Health, Speaks in support  
11:14:32 AM Michael Jackson, FL Pharmacy Association, Waive in opposition  
11:14:40 AM Preston McDonald, Pharmacist, Waives in opposition  
11:14:43 AM Kathy Baldwin, FSHP, waive in opposition  
11:14:55 AM Audrey Brown, FL Assoc of Health Plans, WIS  
11:15:06 AM Sen Hukill Question  
11:15:29 AM Sen Grimsley  
11:16:06 AM Sen Hukill  
11:16:35 AM Sen Grimsley  
11:17:50 AM Chair Young Debate  
11:19:16 AM Sen Grimsley waives close  
11:19:19 AM Roll Call  
11:19:31 AM CS/SB 848 Recorded Favorably  
11:19:49 AM Tab 5 SB 1494  
11:19:59 AM Sen Grimsley  
11:20:18 AM LF AM 167480  
11:20:23 AM Sen Grimsley  
11:21:41 AM Chair Young dismissed  
11:23:19 AM Audrey Brown, FL Assoc of Health Plans, WIS  
11:23:29 AM Handwritten AM  
11:23:36 AM Sen Hutson  
11:23:59 AM HW AM adopted  
11:24:21 AM LF AM 167480 Adopted  
11:24:52 AM James Wright, self, WIS  
11:25:10 AM Bill Mincy, VP PPSC, WIS  
11:25:14 AM Michael Jackson, FL pharmacy association, WIS  
11:25:21 AM Cynthia Henderson, EPIC Pharmacies, WIS  
11:25:32 AM Chris Nuland, FL College of Physicians , WIS  
11:25:37 AM Jeff Scott, FL medical assoc., WIS  
11:25:46 AM Stephen Winn, FL Osteopathic Medicine, WIS  
11:25:53 AM Dr. Suzy Wise, Pharmacist, WIS  
11:26:01 AM Preston McDonald, Pharmacist, WIS  
11:26:14 AM Toni Large, FL Rheumatology, WIS  
11:26:28 AM Kathy Baldwin, Pharmacist FSHP, WIS  
11:26:41 AM Sen Grimsley waives close  
11:26:43 AM Roll Call  
11:26:58 AM CS/SB 1494 Recorded Favorably  
11:27:26 AM Tab 2 SB 524  
11:27:30 AM Sen Brandes  
11:27:50 AM AM 788828  
11:27:55 AM Sen Brandes  
11:29:51 AM Michael Jackson, FL pharmacy association, WIS

11:30:01 AM AM 788828 Adopted  
11:30:22 AM Michael Jackson, FL pharmacy assoc, WIS  
11:30:27 AM Bill Mincy, PPSC, speaks in support  
11:31:25 AM Griff Danheim, Director Specialty Markets, WIS  
11:31:37 AM Dr. Michael Forsthoefel, FL Medical Assoc, speaks against  
11:37:07 AM Stephen Winn, FL osteopathic medical assoc, Waives in opposition  
11:37:25 AM Dr. Suzy Wise, pharmacist, speaks in support  
11:40:04 AM Ameer Diaz Lyon, FL academy of family physicians, Speaks against  
11:40:27 AM Melissa Ramba, FL Retail Federation, speaks in support  
11:41:15 AM Mia Diaz, FL Tax Watch, Waive in support  
11:41:20 AM Toni Large, FL college of emergency physicians, Waive In Opposition  
11:41:25 AM Kathy Baldwin, Pharmacist FSHP, WIS  
11:41:33 AM Dr. Christie Alexander FL academy of family physicians, Waive in opposition  
11:42:00 AM Sen Hukill debate  
11:42:30 AM Sen Passidomo debate  
11:44:30 AM Sen Benacquisto debate  
11:46:19 AM Sen Brandes TPs bill  
11:47:33 AM Tab 3 SB 758  
11:47:48 AM Sen Gibson  
11:49:28 AM AM 920380  
11:49:36 AM Sen Gibson explains amendment  
11:50:15 AM AM 920380 adopted  
11:50:27 AM Sen Benacquisto question  
11:50:46 AM Sen Gibson  
11:51:31 AM Sen Benacquisto  
11:51:52 AM Sen Gibson  
11:52:59 AM Melanie Bostick, american assoc of diabetes educators, WIS  
11:53:05 AM Sen Gibson waives close  
11:53:07 AM Roll Call  
11:53:32 AM CS/SB 758 Recorded Favorably  
11:53:51 AM Tab 1 CS/SB 394  
11:54:06 AM Sen Bracy  
11:54:32 AM LF AM 923612  
11:54:41 AM Sen Passidomo explains amendment  
11:55:19 AM Sen Bracy  
11:55:54 AM Sen Hutson Question  
11:56:03 AM Sen Passidomo  
11:56:49 AM Raul Cernuda, Firefighter, waives in opposition  
11:57:15 AM Rocco Salvatori, FL professional Firefighters, speaks in opposition  
12:00:39 PM Otto Drozd, FL fire chiefs assoc, Speaks in opposition  
12:01:29 PM Eloy Ricardo, FL professional firefighters, WIS  
12:01:35 PM Eric Chudzik, Cape coral fire fighters, WIO  
12:01:41 PM Laurita Sweeney, orange county firefighters assoc., WIO  
12:01:45 PM David Shepard, political committee chair, WIO  
12:01:49 PM Michael Lynch, jacksonville firefighters, WIO  
12:01:52 PM Randy Wyse, Jacksonville firefighters, WIO  
12:01:58 PM Chuck Baldwin, jacksonville firefighter, WIO  
12:02:02 PM Chris Richie, orange county firefighters assoc, WIO  
12:02:06 PM Richard Pienzo, brevard firefighters, WIO  
12:02:11 PM Kurt Vroman, firefighter, WIO  
12:02:15 PM Eric Sienna, VP Orange county firefighters assoc., WIO  
12:02:20 PM Andre Perez, president orange county firefighters assoc., WIO  
12:02:25 PM James Pucci, legislative affairs and liaison, WIO  
12:02:29 PM Kevin Bellury, St lucie firefighters, WIO  
12:02:33 PM Joe Piccao, firefighter, WIO  
12:02:40 PM Eric Johnson, firefighter, WIO  
12:02:44 PM John O'Brien, firefighter, WIO  
12:02:49 PM Dan Givens, fire trustee, WIO  
12:02:56 PM Brian ment, mian, WIO  
12:03:00 PM David Perez, firefighter, WIO  
12:03:03 PM Omar Blanco, President Miami Dade Firefighters, WIO  
12:03:07 PM Jorge Chavez, firefighter, WIO

12:03:11 PM Albert Robert, firefighter WIO  
12:03:27 PM Sen Passidomo close  
12:04:41 PM LF AM Not Adopted  
12:04:57 PM Raul Cernuda, firefighter, WIS  
12:05:00 PM Ryan Ventimiglia, Firefighter, WIS  
12:05:05 PM Dan Givens, fire trustee, WIS  
12:05:08 PM John O'Brien, firefighter, WIS  
12:05:11 PM David Perez, firefighter, WIS  
12:05:15 PM Eric Johnson, firefighter, WIS  
12:05:20 PM David Shepard, Political committee chair, WIS  
12:05:25 PM Laurita Sweeney, orange county firefighters assoc., WIS  
12:05:31 PM Christ Richie, orange county firefighters assoc WIS  
12:05:36 PM Otto Drozd, FL fire chiefs assoc., WIS  
12:05:55 PM Jim Tolley, FL professional firefighters, speaks in support  
12:06:45 PM Richard Pierce, firefighter, WIS  
12:06:49 PM James Pucci, legislative affairs liason, WIS  
12:06:55 PM Kurt Vroman, firefighter, WIS  
12:06:57 PM Andre Perez, President orange county firefighters assoc., WIS  
12:06:59 PM Eric Sienna, VP orange county firefighters assoc., WIS  
12:07:02 PM Kevin Bellury, st lucie firefighters, WIS  
12:07:06 PM Albert Robert, firefighter WIS  
12:07:25 PM Sen Bracy close  
12:07:45 PM Roll Call  
12:08:00 PM SB 394 Recorded Favorably  
12:08:12 PM Chair Young  
12:08:24 PM Tab 6 SB 1508  
12:08:26 PM Sen Young  
12:12:10 PM Sen Young waives close  
12:12:13 PM Roll Call  
12:12:31 PM SB 1508 Recorded Favorably  
12:13:18 PM Adjourned  
12:13:20 PM Recording Paused